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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

CV14-00310-PA(JCGx)

BIOSUCCESS BIOTECH, CO., LTD.,

Plaintiff,

v.

RICH PHARMACEUTICALS, INC., a Nevada Corporation formerly known as Nepia, Inc., IMAGIC, LLC, a California LLC, RICHARD L. CHANG HOLDINGS LLC, a New Jersey LLC, BEN CHANG, an individual, and DOES 1 through 10, inclusive,

Defendants.

Case No.

COMPLAINT FOR:

1. PATENT INFRINGEMENT
2. COPYRIGHT INFRINGEMENT
3. MISAPPROPRIATION OF TRADE SECRETS
4. BREACH OF FIDUCIARY DUTY
5. STATUTORY UNFAIR COMPETITION
6. COMMON LAW UNFAIR COMPETITION
7. VIOLATION OF CAL. PENAL CODE SECTION 502
8. TRESPASS TO CHATTELS
9. INDUCING BREACH OF CONTRACT
10. INDUCING BREACH OF FIDUCIARY DUTY
11. CONVERSION
12. CONSPIRACY
13. AIDING AND ABETTING

JURY TRIAL DEMANDED

Plaintiff Biosuccess Biotech Co. Ltd., ("Plaintiff" or "Biosuccess") alleges the following against Defendants RICH PHARMACEUTICALS, INC., IMAGIC, LLC, RICHARD L. CHANG HOLDINGS LLC, BEN CHANG, and DOES 1 through 10, inclusive.

PARTIES

1. Plaintiff Biosuccess Biotech, Co., Ltd. ("Biosuccess") is a corporation organized under the laws of the Cayman Islands, with its principal place of business in Taipei, Taiwan.

2. On information and belief, Defendant Rich Pharmaceuticals, Inc. ("Rich Pharmaceuticals") is a corporation organized under the laws of the State of Nevada, with its principal place of business at 9595 Wilshire Blvd., Suite 900, Beverly Hills, California, 90212. Defendant Rich Pharmaceuticals was formerly known as Nepia, Inc. ("Nepia"), a publicly traded corporation on NASDAQ, organized under the laws of the State of Nevada as of August 9, 2010.

3. On information and belief, before July 2013, Nepia was engaged in developing, manufacturing, and selling small boilers. On information and belief, some time in 2012 or 2013, Rich Pharmaceuticals merged with Nepia. On or around September 3, 2013, Nepia changed its name to Rich Pharmaceuticals, and now has its principal place of business at 9595 Wilshire Blvd., Suite 900, Beverly Hills, California, 90212.

4. On information and belief, Defendant Imagic, LLC ("Imagic") is a LLC registered in the State of California. Imagic's agent for service of process is Ben Chang, 9595 Wilshire Blvd., Suite 900, Beverly Hills, California, 90212.

5. On information and belief, Defendant Richard L. Chang Holdings LLC ("RLC Holdings") is a LLC registered in the State of New Jersey, with a place of business at 107 Konner Avenue, Pine Brook, New Jersey 07058. On information and belief, third party Richard Chang is the sole officer and manager of RLC Holdings, and is a resident of Laguna Woods, California.

6. On information and belief, Defendant Ben Chang is an individual residing at 312 North Mansfield Avenue, Los Angeles, California, 90036.

7. The true names or capacities of defendants named herein as DOES 1 through 10 are presently unknown to Biosuccess. Therefore, Biosuccess sues said defendants by such fictitious names, and will amend this Complaint to show their true names and capacities when the same has been ascertained. Biosuccess is informed and believes, and based on such information and belief, alleges that defendants sued as DOES 1 through 10, and each of them, are liable in whole or in part for the wrongful acts alleged herein.

8. On information and belief, each Defendant, including DOES 1 through 10, inclusive, have willfully aided and abetted each of the other Defendants in the wrongful concerted action described herein, or acted with or in furtherance of that action, or assisted in carrying out its purpose alleged in this Complaint.

9. Defendants, and each of them, are individually sued as participants and aiders and abettors in the wrongful conduct complained of herein, and the liability of each arises from the fact that each has engaged in all or part of the improper acts, plans, schemes, conspiracies, or transactions complained of herein.

JURISDICTION AND VENUE

10. This is a civil action for patent infringement arising under the laws of the United States, 35 U.S.C. Section 1 *et seq.* This Court has subject matter jurisdiction over such Federal Question claims pursuant to 28 U.S.C. Sections 1331 and 1338(a).

11. This Court also has Federal Question jurisdiction over the copyright and unfair competition causes of action asserted in this Complaint pursuant to 28 U.S.C. Section 1338 and 17 U.S.C. Section 301(a).

12. This Court has supplemental jurisdiction over the other claims asserted in this Complaint pursuant to 28 U.S.C. Section 1367.

13. Venue is proper in this Judicial District under 28 U.S.C. Sections 1391

and 1400(b).

14. This Court has personal jurisdiction over the defendants because they are either residence of the State of California and/or have sufficient minimum contacts such that the exercise of jurisdiction over each would not offend traditional notions of fair play and substantial justice.

FACTUAL BACKGROUND

A. Biosuccess is the Leader in TPA Research

15. Founded in 2005, Biosuccess is a promising biomedical research and development company dedicated to researching 12-O-tetradecanoylphorbol-13-acetate, also known as "TPA," for the treatment and applications of, *inter alia*, acute myelogenous leukemia ("AML"), AIDS/HIV for patients who were refractory to standard therapy, and stroke. Biosuccess gave TPA a unique designated name of "PD-616." Biosuccess's main goals are to supply drugs to the global market and to obtain both domestic and foreign patent protection.

16. Biosuccess has spent considerable time and effort, as well as millions of dollars towards the research and development of PD-616 for the treatment of AML and stroke, as well as numerous other treatment applications, and has complied valuable research and business data ("Confidential Information"). Biosuccess's main research operations are based in China under the supervision of Dr. Zheng Tao ("Dr. Han") and other research scientists. Biosuccess uses the Confidential Information for, among other things, submissions to the U.S. Food and Drug Administration ("FDA"), and as a basis for filing both domestic and foreign patent applications. Biosuccess's Confidential Information is not public or generally known.

17. Biosuccess's Confidential Information is contained in various documents and electronic files. Biosuccess takes great care to maintain the secrecy of its Confidential Information and to prevent disclosure to persons outside the Company, including requiring employees to sign a non-disclosure agreement and

abide by the Employee Handbook.

18. Based on Biosuccess's clinical results, Biosuccess has been involved with two clinical studies. The first is NCT01009931, titled "Phase II Study of TPA Plus Dexamethasone & CMT in Hematologic Malignancies," and the second is NCT01795924, titled "Safety and Efficacy Study of PD-616 Plus Cytarabine to Treat Acute Myelogenous Leukemia or Myelodysplastic Syndrome (AML/MDS)."

B. Relevant Employment Agreements

19. During all relevant times, third party Richard Chang was a shareholder, officer, employee, and a member of the Board of Directors of Biosuccess from around August 2006 to January 2013. Although Richard Chang did not contribute to Biosuccess's research data, he had complete and widespread knowledge and access to all of Biosuccess's most sensitive trade secrets, including years of research data related to PD-616 and its proprietary formulations.

20. Defendant Ben Chang is the son of Richard Chang. In 2006, Ben Chang became a consultant for Biosuccess. In 2011, Ben Chang was employed by Biosuccess as its President for the North America operation. In his capacity both as a consultant and the operating officer, Ben Chang had complete and widespread knowledge and access to all of Biosuccess's most sensitive trade secrets, including years of research data related to PD-616 and its proprietary formulations.

21. As a condition of their employment, Richard Chang and Ben Chang were all obligated to protect Biosuccess's confidential business information and trade secrets. For instance, Biosuccess's Employee Handbook provides, in pertinent part, that:

a. The information protected includes, among other things, "new product research, pending projects and proposals, proprietary production processes, research and development strategies, [and] scientific data."

b. Employees agreed that they would "only share such information with those individuals who have authorized access with prior written approval, from

Biosuccess' Chief Financial Officer."

c. Employees agreed that upon termination of employment that they must return all Biosuccess property.

22. On or around January 1, 2013, Ben Chang was asked by Biosuccess to turn in his work related computer provided by Biosuccess and to preserve all information, including any emails. Ben Chang refused to cooperate and instead erased the entire contents of his work related computer, including deleting all emails.

23. On information and belief, during his employment as Biosuccess's consultant and officer, Ben Chang amassed most, if not all, of Biosuccess's research data related to PD-616 and its proprietary formulations. Ben Chang then transferred and took this data from Biosuccess in violation of his obligations and without Biosuccess's knowledge.

24. On information and belief, Richard Chang, Ben Chang, and other unknown Doe Defendants conspired together to steal Biosuccess's most sensitive trade secrets for their own benefit and against Biosuccess's interests.

C. Defendants Conspired to Destroy Biosuccess by Stealing its Intellectual Property and Confidential Information

25. Beginning in 2012 and continuing through today, on information and belief, Richard Chang, Ben Chang, and other unknown Doe Defendants conspired to destroy Biosuccess through unethical and outrageous behavior, including spreading untrue and misleading statements to the employees of the U.S. Subsidiary regarding the financial state of the company, and disclosed confidential business information to others, including the company's payroll information. They also made repeated attempts to induce Dr. Han to take his research and data and defect with them to outside investors, by offering Dr. Han millions of dollars in return.

26. Without authorization, Defendant Ben Chang registered himself as a

managing member of Biosuccess's U.S. subsidiary.

27. In furtherance of the conspiracy and plan to destroy Biosuccess, on information and belief Ben Chang approached and brought in Nepia. On or around July 18, 2013, according to Nepia's S.E.C. filings, Nepia entered into a Memorandum of Understanding and Asset Assignment Agreement with Defendant Imagic and Defendant RLC Holdings to acquire certain alleged assets including United States Patent No. 6,063,814, entitled "Phorbol esters as anti-neoplastic and white blood cell elevating agents" and all related intellectual property associated with the patent. According to the SEC filings, cash and stock were exchanged in return.

28. In July 18, 2013, Nepia appointed Ben Chang as its President, Chief Executive Officer, Chief Financial Officer, Secretary, Treasurer and Director.

29. Nepia represented in its S.E.C. filings that "Under the direction of our newly appointed officer and director . . . we intend to pursue the development of PD-616 (12-O-tetradecanoylphorbol-13-acetate) for the treatment of: Acute Myelogenous Leukemia ("AML") and Stroke (for the treatment of loss of function cause by Stroke) . . . ."

30. Nepia stated in its S.E.C. filings that "The priority drug development efforts of the Company are focused on the use of PD-616, a naturally occurring compound that has a number of properties that are uniquely suited for the treatment of patients with Acute Myelocytic Leukemia (AML). Company scientists had worked with PD-616 in the laboratory for many years studying its ability to convert cancer cells to normal cells, a process called differentiation. It was also observed in some instances to cause cancer cell death. These observations were the basis of the proposal to test PD-616 in relapsed AML patients in China and later in the US and resulted in findings that were sufficiently encouraging to support further interest in this drug to treat."

31. In fact, Nepia has performed none of the drug development or work

stated in the aforesaid S.E.C. filings. Instead, the drug development and clinical work involving PD-616 and its treatment of AML was a result of work funded and performed by Biosuccess. PD-616 is the unique name created by Biosuccess for the new drug and is Biosuccess's proprietary property.

32. On or around August 12, 2013, third party Richard Chang recorded with the U.S. Patent and Trademark Office an assignment of United States Patent No. 6,063,814 ("the '814 Patent") and United States Application Nos. 13/745,745 and 13/745,740 to RLC Holdings. The contact person and correspondence address for the assignment is his son, Defendant Ben Chang, 312 North Mansfield Avenue, Los Angeles, California 90036. Richard Chang also appointed a Power of Attorney to Ben Chang.

33. However in 2006, Richard Chang had already assigned all his rights under the '814 Patent to Biosuccess by an agreement titled, "Assignment of Patent Right & Assignment of Right of Patent Application Agreement." Said assignment agreement was first recorded on November 14, 2006. That assignment is the subject of the pending litigation in this District, Case No. CV13-01340-JAK.

34. On or around September 3, 2013, Nepia changed it name to Rich Pharmaceuticals, Inc.

35. On September 6, 2013, Ben Chang entered into an employment agreement with Rich Pharmaceuticals, Inc. as its President, Chief Executive Officer, Chief Financial Officer, and Secretary. Ben Chang was also appointed one of two directors of Rich Pharmaceuticals, Inc.

36. Ben Chang oversaw the operation of Biosuccess's entire U.S. operation and was the key (if not sole) person of contact for most of the operation, from patent filings, financial management and clinical trials. Ben Chang controlled Biosuccess's Confidential Information and is using Biosuccess's Confidential Information in his role as President, Chief Executive Officer, Chief Financial Officer, Secretary and Director at Rich Pharmaceuticals, including conducting

clinical trials at two sites in the U.S., meeting with the top ranking foreign health officers, maintaining Rich Pharmaceuticals's patent portfolio, and preparing submissions to the FDA.

37. At the direction of Ben Chang, and with the explicit cooperation of third party Richard Chang, Rich Pharmaceuticals, Inc. engages in direct competition with Biosuccess, including by selling, offering to sell, and/or importing products in the United States inventions claimed by the '814 Patent.

D. Defendants Copy the Biosuccess Website

38. Biosuccess first published its website on or about 2006, and applied for a copyright registration in late 2013.

39. Starting around 2011, without Biosuccess's knowledge or authorization, on information and belief at the direction of Defendants, a web designer named Ben Alamilla began copying the Biosuccess website, *verbatim*.

40. On information and belief, on or around October 18, 2013, Rich Pharmaceuticals published its website at www.richpharmaceuticals.com. Upon reviewing the website, it became immediately obvious to Biosuccess that Defendants had wholesale copied large portions of the copyrighted Biosuccess website. For example, the Rich Pharmaceuticals "About Us" webpage is copied nearly verbatim from the Biosuccess "About Us" webpage. True and correct copies of the screenshots of Rich Pharmaceuticals "About Us" webpage and Biosuccess "About Us" webpage are attached as Exhibit A to this Complaint. Upon further investigation, Biosuccess discovered that Rich Pharmaceuticals had used the Biosuccess website as a "template" for creating the Rich Pharmaceuticals website. A true and correct copy of the screenshot of Rich Pharmaceuticals "About Us" by Ben Alamilla is attached as Exhibit B to this Complaint.

41. As the chart below shows, Rich Pharmaceuticals's website is verbatim or nearly identical to Biosuccess's website in many key aspects:

Page Description	Biosuccess Website	Rich Pharmaceuticals Website
About Us	**About Us** Founded in 2005, Biosuccess Biotech Co. Ltd. is a privately held company. It focuses on the development of PD-616 (12-O-tetradecanoylphorbol-13-acetate, also known as TPA) for the treatment of AML and AIDS/HIV. The work of two scientists, Prof. Richard Chang & Prof. Zhang Tao Han sustained by their knowledge of this agent's characteristics and their wide experience of years is the basis for the company's interest in using PD-616 in treatment.	**About Us** Rich Pharmaceuticals is a biopharmaceutical company that became a public entity August 26, 2012 as a result of a reverse merger with Nepia Inc. The Company is focused on the development of its lead product, TPA (12-O-tetradecanoylphorbol-13-acetate), for the treatment of acute myelogenous leukemia (AML) in refractory patients, and the reversal of physical disabilities resulting from stroke. The basis for the interest of the Company to pursue clinical development of TPA in these and possibly other indications is the result of the work of two scientists, Prof. Richard Chang and Prof. Zhang Tao Han. Both have conducted research on TPA for many years and have become experts in the characteristics of this molecule. Their findings form the scientific basis for the clinical use of TPA.
About Us	**AML Studies with TPA (PD-616)** Clinical studies were conducted in China in patients who had few (sometimes none) remaining options for therapy in acute myelogenous leukemia (AML).	**AML Studies with TPA** Initially, clinical studies were conducted in leading hospitals in China in patients who had few, if any, options remaining for the treatment AML.
About Us	**AML Studies with TPA (PD-616)**	**AML Studies with TPA** These patients were refractory

	These patients were refractory to standard therapy and had debilitating symptoms.	to standard therapy and had debilitating symptoms that were life threatening.
About Us	**AML Studies with TPA (PD-616)** Findings showed that some patients were put into partial remission and established the short term safety for the intravenous administration of PD-616.	**AML Studies with TPA** The clinical status of some of the patients treated with TPA changed favorably to partial remission. In addition, the short term safety of TPA was established in these individuals using an intravenous formulation of TPA.
About Us	**AML Studies with TPA (PD-616)** Encouraged by the clinical results from China, Roger Strair MD, PhD, a leading oncologist at The Cancer Institute of New Jersey (CINJ), at the University of Medicine and Dentistry of N.J. (UMDNJ), obtained an investigator IND, and conducted a Phase 1 study in patients the majority of whom also had relapsed/refractory AML.	**AML Studies with TPA** Encouraged by the clinical results with TPA in China, Roger Strair MD, PhD, a leading oncologist at the University of Medicine and Dentistry at Rutgers University, obtained an investigator IND and successfully completed a Phase 1 study in patients, the majority of whom had relapsed/refractory AML.
About Us	**AML Studies with TPA (PD-616)** Based on Phase 1 findings, Biosuccess Biotech was encouraged by Dr. Strair to conduct a Phase 2 study in relapsed/refractory AML.	**AML Studies with TPA** Rich Pharmaceuticals was encouraged by Dr. Strair to conduct a Phase 2 study in relapsed/refractory AML.
About Us	**AML Studies with TPA (PD-616)** Currently, a Phase 2 study is underway and the recruitment of refractory AML patients is actively done by Dr. Strair.	**AML Studies with TPA** A Phase 2 study is currently underway under the direction of Dr. Strair who is actively enrolling appropriate patients in this study.
About Us-	**Legal Grounds**	**Legal Grounds**

Legal Grounds	Biosuccess Biotech is protected by an issued "use patent" that provides sole rights to use the intravenous administration of PD-616 for therapeutic purposes (2001).	Rich Pharmaceuticals is protected by an issued "use patent" that gives sole rights to the Company to use the intravenous administration of TPA for therapeutic purposes.
Technology	**Technology** Biosuccess Biotech Co. Ltd. pursues the development of TPA (12-O-tetradecanoylphorbol-13-acetate) for the treatment of AML and HIV/AIDS. TPA is often referred to as PD-616 or PMA (phorbol 12-myristate-13-acetate).	**Our Science** Rich Pharmaceuticals currently is focused on the clinical development of the chemical molecule TPA (12-O-tetradecanoylphorbol-13-acetate) for the treatment of acute myelogenous leukemia (AML).
Technology	**PD-616** PD-616 has been widely studied for characteristics that are unique to this chemical class among which are a potent ability to accelerate differentiation of the myeloid cell lines, HL-60 and THP-1, as well as mononuclear phagocytes from bone marrow and peripheral blood.	**TPA** TPA has characteristics that are unique to this chemical class including a potent ability to accelerate differentiation of the myeloid cell lines, HL-60 and THP-1, as well as mononuclear phagocytes from bone marrow and peripheral blood.
Technology	**PD-616** The best characterized receptor for PD-616 is protein kinas C (PKC) which, once activated, induces substrate phosphorylation that propagates signals to MAPK cascades.	**TPA** The best characterized receptor for TPA is protein kinase C (PKC) which, once activated, induces substrate phosphorylation that propagates signals to the MAPK cascades.
Technology	**PD-616** The effect of PD-616 on MAPK pathways may be particularly relevant to the differentiating and	**TPA** The effects of TPA on MAPK pathways may be particularly relevant to the differentiating

	pro-apoptotic effects of PD-616 in certain cells.	and pro-apoptotic effects of TPA in certain cells.
Technology	**PD-616** The capacity of PD-616 to activate PKC and to induce phenotypic changes characteristic of differentiation and/or apoptosis led investigators to study its effect in AML and HIV/AIDS.	**TPA** The capacity of TPA to activate PKC and to induce phenotypic changes characteristic of differentiation and/or apoptosis led investigators to study its effect in AML.

FIRST CAUSE OF ACTION

(Patent Infringement)

Against Rich Pharmaceuticals, Ben Chang, Imagic LLC, Richard L. Chang's Holding LLC and DOES 1-10

42. Biosuccess incorporates by reference the paragraphs above as if fully set forth herein.

43. On May 21, 2000, U.S. Patent No. 6,063,814 (the "'814 Patent"), was issued by the United States Patent and Trademark Office ("USPTO"). A true and correct copy of the '814 Patent is attached as Exhibit C to this Complaint.

44. Biosuccess is the assignee and owner of the right, title and interest in and to the '814 Patent, including the right to assert all causes of action arising under said patent and the right to any remedies for infringement of it.

45. In violation of 35 U.S.C. § 271, Defendants have directly infringed and continue to directly infringe, literally and/or under the doctrine of equivalents, the '814 Patent by making, using, selling, offering to sell, or importing in the United States, including in this Judicial District, inventions claimed by the '814 Patent, ("the '814 Accused Products and Uses"), without authority of Biosuccess.

46. The '814 Accused Products and Uses, include, but are not limited to, PD-616 and/or TPA for the use in treating victims of, among other indications,

leukemia and stroke.

47. Defendants have had actual knowledge of the '814 Patent since it was filed with the USPTO, and of its infringement since at least July 18, 2013, when Nepia entered into a Memorandum of Understanding and Asset Assignment Agreement with Defendant Imagic and Defendant RLC Holdings to acquire certain alleged assets including the '814 Patent and all related intellectual property associated with the patent.

48. Upon information and belief, Defendants have committed and continue to commit acts of contributory infringement of the '814 Patent under 35 U.S.C. §271(c) by selling, offering to sell, and/or importing products, including the '814 Accused Products and Uses, knowing or willfully blind to the fact that these products and use constitute a material part of the invention, were especially made or especially adapted for use in an infringement of the '814 Patent, and have no substantial non-infringing uses.

49. Upon information and belief, Defendants have induced and continue to induce others to infringe the '814 Patent under 35 U.S.C. § 271(b) by, among other things, and with specific intent, actively and knowingly aiding and abetting others to infringe, including, but not limited to, those whose use of the '814 Accused Products and Use that constitutes direct infringement of the '814 Patent. On information and belief, Defendant engaged in such actions with specific intent to cause infringement or with willful blindness to the resulting infringement because Defendants have had actual knowledge of the '814 Patent and that its acts were inducing others to infringe the '814 Patent.

50. As a result of Defendants' infringement of the '814 Patent, Biosuccess has suffered both monetary damages and other damages that cannot be compensated by monetary damages. Biosuccess will continue to suffer damages in the future unless Defendants' infringing activities are enjoined by this Court.

51. Unless a permanent injunction is issued enjoining Defendants from

infringing the '814 Patent, Biosuccess will be greatly and irreparably harmed.

SECOND CAUSE OF ACTION

(Copyright Infringement)

Against Rich Pharmaceuticals, Ben Chang, and Does 1-10

52. Biosuccess incorporates by reference the paragraphs above as if fully set forth herein.

53. Rich Pharmaceuticals is infringing Biosuccess's copyrighted website in violation of the Copyright Act by its wholesale copying and re-publishing of Biosuccess's website on its www.richpharmaceuticals.com website. The Rich Pharmaceuticals website is substantially similar, if not identical, to Biosuccess's own website.

54. On information and belief, Defendants' infringement has been deliberate, willful, malicious, oppressive, and without regard to Biosuccess's proprietary rights.

55. On information and belief, Defendant Ben Chang has been personally involved in directing and causing Rich Pharmaceuticals to engage in its copyright infringement of Biosuccess's website.

56. Defendants' copying of the Biosuccess website without Biosuccess's authority or consent and is also in violation of the Employee Handbook, and is in willful and conscious disregard of Biosuccess's rights under the federal Copyright Act.

57. Defendants' copyright infringement has caused, and will continue to cause, Biosuccess to suffer substantial injuries, loss, and damage to its proprietary and exclusive rights and has further damaged Biosuccess's business reputation and goodwill, diverted its trade, and caused loss of profits, all in an amount to be determined. In addition, Plaintiff Biosuccess is entitled to receive the profits made by Defendants from their wrongful acts pursuant to 17 U.S.C. Section 504.

58. In infringing Biosuccess's copyright interests, Defendants acted

willfully and maliciously, entitling Biosuccess to enhancement of any statutory damages, pursuant to 17 U.S.C. § 504(c)(2), in an amount to be determined at trial.

59. Defendants' copyright infringement and the threat of continuing infringement has caused and will continue to cause Biosuccess repeated and irreparable injury. It would be difficult to ascertain the amount of money damages that would afford Biosuccess adequate relief at law for Defendants' acts and continuing acts. Plaintiff's remedy at law is not adequate to compensate it for the injuries already inflicted and further threatened by Defendants. Therefore, Plaintiff is entitled to preliminary and permanent injunctive relief pursuant to 17 U.S.C. Section 502.

60. As a direct and proximate result of Defendants' willful infringement of Biosuccess's copyright interests, Biosuccess has had to retain legal counsel, and it is entitled to recover its attorneys' fees from Defendants pursuant to 17 U.S.C. § 505, as well as costs, including any expert fees that might be appropriately recoverable.

THIRD CAUSE OF ACTION

(Misappropriation of Trade Secrets – Cal. Civ. Code § 3426.1 et seq.)

Against All Defendants

61. Biosuccess incorporates by reference the paragraphs above as if fully set forth herein.

62. Biosuccess is informed and believes, and on that basis alleges, that Defendants are using Biosuccess's Confidential Information, without Biosuccess's consent, to unlawfully compete against Biosuccess.

63. Biosuccess enjoys an advantage over its existing and would-be-competitors based, in part, on the trade secret information it has developed and implemented in its effort to bring PD-616 to market for the treatment of, among other diseases, leukemia and stroke.

64. Biosuccess has made reasonable efforts under the circumstances to

preserve the confidentiality of its trade secrets. Such information derives independent economic value (actual and potential) from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use. Accordingly, the above-described Confidential Information constitutes "trade secrets" under California's UTSA, Cal. Civ. Code Section 3426 *et seq*.

65. Defendants were and remain under a duty both to keep Biosuccess's confidential, proprietary or trade secret information secret, and not to use or disclose such information other than for the benefit of Biosuccess and only with Biosuccess's authorization. By taking or using this information from Biosuccess without its authorization, Defendants knew or should have known that they acquired such information under circumstances giving rise to a breach of a duty to maintain its secrecy and limit its use.

66. Defendants conduct constitutes misappropriation of Biosuccess's trade secrets through the unauthorized taking, retention and use of Biosuccess's trade secret information.

67. Defendants' actual and threatened misappropriation was and is being carried out without the express or implied consent of Biosuccess.

68. On information and belief, Defendants obtained the Confidential Information described above directly or indirectly from Biosuccess and not generally available information or through its own independent research and efforts.

69. The actions of Defendants constitute willful misappropriation and/or threatened misappropriation of Biosuccess's trade secrets under the California's UTSA, Cal. Civ. Code Section 3426 *et seq*.

70. As a direct and proximate result of Defendants' conduct, Defendants have been unjustly enriched in an amount to be ascertained at trial, and Biosuccess has sustained, and will continue to sustain, actual damages in an amount to be proven at trial.

71. Defendants' actual and threatened misappropriation of Biosuccess's

trade secrets, unless and until enjoined and restrained by order of this Court, is causing and will continue to cause great and irreparable harm to Biosuccess. Biosuccess is threatened with losing its intellectual property, as well current and potential business and investors.

72. Pursuant to California Civil Code section 3426.2, Biosuccess is entitled to an injunction to prohibit Defendants from using, disclosing or otherwise benefiting from Biosuccess's trade secrets, to eliminate any commercial advantage to Defendants that they may otherwise derive from their misappropriation, and to require Defendants to immediately return to Biosuccess all information, equipment and other materials which they have wrongfully obtained.

73. In performing the conduct described herein, Defendants acted willfully and maliciously with the intent to injure Biosuccess and to wrongfully advantage themselves at Biosuccess's expense.

74. Pursuant to California Civil Code section 3426.3(c), Biosuccess is entitled to an award of punitive and exemplary damages against Defendants, and each of them, sufficient to punish and deter them from engaging in such conduct in the future, in an amount to be ascertained at trial.

75. Pursuant to California Civil Code section 3426.4, Biosuccess is also entitled to an award of their attorneys' fees and costs incurred in this action.

FOURTH CAUSE OF ACTION

(Breach of Fiduciary Duty)

Against Ben Chang

76. Biosuccess incorporates by reference the paragraphs above as if fully set forth herein.

77. As an officer of Biosuccess, Ben Chang was entrusted with maintaining a variety of confidential information and overseeing certain special projects at Biosuccess. Accordingly, Ben Chang owed Biosuccess a duty of loyalty. Ben

Chang breached his duty of loyalty by the actions described above.

78. As a direct and proximate result of Ben Chang's breach of his duty of loyalty, Biosuccess has suffered, and will continue to suffer, substantial monetary damages in an amount to be proven at trial.

79. As a condition of his employment with Biosuccess, Biosuccess entrusted its trade secrets and other confidential and proprietary information to Ben Chang and reposed confidence in him that he would not disclose the information or use it for his own personal gain. The trust and confidence Biosuccess reposed in Ben Chang gave rise to a fiduciary duty not to disclose Biosuccess's trade secrets and confidential information or use them for personal gain.

80. Biosuccess is informed and believes, and on that basis alleges, that Ben Chang has breached this fiduciary duty by disclosing Biosuccess's trade secrets and other confidential information to Rich Pharmaceuticals and by utilizing Biosuccess's trade secrets and confidential information, without Biosuccess's consent, in connection with Rich Pharmaceuticals.

81. Indeed, in practical terms, it is impossible for Ben Chang to develop and be in the same footing as Biosuccess without breaching his fiduciary duty not to disclose protected information.

82. As a direct and proximate result of Ben Chang's breach of this fiduciary duty, Biosuccess has been damaged in an amount to be proved at trial.

83. Biosuccess is entitled to an award of punitive and exemplary damages against Ben Chang sufficient to punish and deter them from engaging in such conduct in the future, in an amount to be ascertained at trial.

FIFTH CAUSE OF ACTION

(Unfair Competition Pursuant to California Business and Professions Code Section 17200, et seq.)

Against All Defendants

84. Biosuccess incorporates by reference the paragraphs above as if fully set forth herein.

85. Biosuccess is informed and believes, and on that basis alleges, the above-described conduct of the Defendants constitutes unlawful and unfair business practices in violation of California Business and Professions Code Section 17200, *et seq*.

86. Defendants' unlawful business practices include, without limitation, Defendants' infringement of Biosuccess's patent and copyright interests, misappropriation of Biosuccess's trade secrets, acts of conversion, breaches of fiduciary duty, and other wrongs described herein.

87. Defendants have acted deliberately with the intent to unfairly benefit from the expense, time, effort and labor expended by Biosuccess in the research and development of PD-616 and its confidential intellectual property related thereto, and with a callous disregard for Biosuccess's rights.

88. Pursuant to California Business and Professions Code Section 17203, Defendants are required to restore to Biosuccess all property acquired by means of Defendants' unfair competition with Biosuccess.

89. As a result of Defendants' conduct, Defendants have been or will be unjustly enriched in an amount to be proven at trial, for which Biosuccess seeks restitution.

90. As a result of the actions of Defendants, Biosuccess has suffered and will continue to suffer irreparable harm unless and those unlawful business practices will continue to cause such irreparable harm until Defendants' conduct is enjoined.

SIXTH CAUSE OF ACTION

(Unfair Competition under California Common Law)

Against All Defendants

91. Biosuccess incorporates by reference the paragraphs above as if fully

set forth herein.

92. The above-described conduct of the Defendants constitutes unfair competition under the common law of the State of California.

93. Because Defendants' conduct has been intentional and willful and in conscious disregard of the rights of Biosuccess, Biosuccess is entitled to punitive damages against Defendants.

SEVENTH CAUSE OF ACTION

(Violation of Cal. Pen. Code § 502)

Against Ben Chang

94. Biosuccess incorporates by reference the paragraphs above as if fully set forth herein.

95. Cal. Pen. Code §502(c) prohibits an individual from knowingly accessing and without permission altering, damaging, deleting, destroying, disrupting, or otherwise using a computer system or computer network. It also prohibits an individual from assisting or providing a means to violate §502(a).

96. As alleged above, before he was terminated, Ben Chang destroyed and erased all of the computer files in the Biosuccess system related to the U.S. operations.

97. Biosuccess is continuing to spend money to investigate the extent of damage caused by Ben Chang's malicious actions, to verify the Biosuccess's information system was or was not otherwise altered and the extent of the information deleted and/or destroyed by Ben Chang.

98. Biosuccess has suffered and will continue to suffer injury to its business, including but not limited to its computer system. Pursuant to Cal. Pen. Code §502(e), Biosuccess seeks injunctive relief, compensatory damages, attorneys' fees, and punitive or exemplary damages.

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EIGHTH CAUSE OF ACTION

(Trespass to Chattels)

Against Ben Chang

99. Biosuccess incorporates by reference the paragraphs above as if fully set forth herein.

100. Biosuccess owns computers in its system network, including the computer assigned to Ben Chang before he was terminated in January 2013.

101. The files on Biosuccess's internal system network, as well as the files on the hard disk drive of the computer assigned to Ben Chang before he was terminated in January 2013, are comprised of data files which Biosuccess possessed and/or had a right to possess.

102. Ben Chang intentionally and without authorization interfered with Biosuccess's possessory interest in said computers on the Biosuccess system network, as well as the files on the Biosuccess system network, and the files on the hard disk drives. Prior to his departure from Biosuccess and without authorization, Ben Chang deleted files from the laptop that had been assigned to her by Biosuccess so that the files were not recoverable.

103. Ben Chang's unauthorized and malicious actions proximately resulted in damages to Biosuccess.

NINTH CAUSE OF ACTION

(Inducing Breach of Contract)

Against Rich Pharmaceuticals, Imagic, and RLC Holdings

104. Biosuccess incorporates by reference the paragraphs above as if fully set forth herein.

105. On information and belief, third party Richard Chang and Ben Chang signed valid and binding non-disclosure agreements prohibiting those individuals from, among other things, disclosing or exploiting the trade secrets and other

confidential information they learned while working at Biosuccess.

106. Biosuccess is informed and believes, and on that basis alleges, that Rich Pharmaceuticals, Imagic, and RLC Holdings knew of the existence of these non-disclosure agreements because, among other things, they are customary in the industry and they use similar non-disclosure agreements in connection with their own research and development.

107. Biosuccess is informed and believes, and on that basis alleges, that Rich Pharmaceuticals, Imagic, and RLC Holdings intended to cause, and in fact caused, these individuals to breach these non-disclosure agreements by encouraging them to disclose Biosuccess's trade secrets and other proprietary and confidential information and methods.

108. Moreover, Biosuccess is informed and believes, and on that basis alleges, that Rich Pharmaceuticals, Imagic, and RLC Holdings knew that their actions would induce a breach of contract, because, in practical terms, it is impossible for the individuals to research and develop PD-616 without breaching their contractual obligations not to disclose or utilizing protected information.

109. As a direct and proximate result of Rich Pharmaceuticals, Imagic, and RLC Holdings inducing these individuals to breach their non-disclosure agreements, Biosuccess has been damaged in an amount to be proved at trial.

110. This knowing and purposeful disregard for Biosuccess's rights under the non-disclosure agreements is oppressive and malicious. Biosuccess is informed and believes, and on that basis alleges, that officers, directors, or managing agents of Rich Pharmaceuticals, Imagic, and RLC Holdings had advance knowledge of these oppressive and malicious acts and consciously disregarded them or authorized, ratified, or perpetrated the oppressive and malicious acts themselves. As a result of such conduct, Biosuccess is entitled to punitive damages pursuant to California Civil Code § 3294 in an amount to be proved at trial.

TENTH CAUSE OF ACTION

(Inducing Breach of Fiduciary Duty)

Against Rich Pharmaceuticals, Imagic LLC, and RLC Holdings

111. Biosuccess repeats and incorporates by reference the allegations in the paragraphs above, as if fully set forth herein.

112. By virtue of their non-disclosure agreements, their status as officers, and the trust and confidence Biosuccess reposed in them in entrusting its trade secrets and other confidential and proprietary information to them, third party Richard Chang and Ben Chang owed Biosuccess a fiduciary duty not to disclose the trade secrets and confidential information they learned while working at Biosuccess.

113. Biosuccess is informed and believes, and on that basis alleges, that Rich Pharmaceuticals, Imagic, and RLC Holdings knew of the existence of the non-disclosure agreements and of the fiduciary duties owed to Biosuccess.

114. Biosuccess is informed and believes, and on that basis alleges, that in connection with the research and development of PD-616 at Rich Pharmaceuticals, Rich Pharmaceuticals, Imagic, and RLC Holdings intended to cause, and in fact caused, these individuals to breach this fiduciary duty by encouraging them to disclose Biosuccess's trade secrets and other confidential information to Rich Pharmaceuticals, Imagic, and RLC Holdings.

115. Biosuccess is informed and believes, and on that basis alleges, that Rich Pharmaceuticals, Imagic, and RLC Holdings knew that their actions would induce a breach of these individuals' fiduciary duties, because, in practical terms, it is impossible for them to research, develop, and produce PD-616 without breaching their fiduciary duty not to disclose or utilizing protected information.

116. As a direct and proximate result of Rich Pharmaceuticals, Imagic, and RLC Holdings inducing third party Richard Chang and Ben Chang to breach their non-disclosure agreements and fiduciary duties, Biosuccess has been damaged in an amount to be proved at trial.

117. This knowing and purposeful disregard for Biosuccess's rights is oppressive and malicious. Biosuccess is informed and believes, and on that basis alleges, that officers, directors, or managing agents of Rich Pharmaceuticals, Imagic, and RLC Holdings either had advance knowledge of these oppressive and malicious acts and consciously disregarded them or authorized, ratified, or perpetrated the oppressive and malicious acts themselves. As a result of such conduct, Biosuccess is entitled to punitive damages pursuant to California Civil Code § 3294 in an amount to be proved at trial.

ELEVENTH CAUSE OF ACTION

(For Conversion)

Against All Defendants

118. Biosuccess repeats and incorporates by reference the allegations in the paragraphs above, as if fully set forth herein.

119. Biosuccess jointly developed and is an owner of the trade secrets and other confidential and proprietary information involved with the research and development of PD-616.

120. Biosuccess is informed and believes, and on that basis alleges, that, in the course of working on the research and development of PD-616 in direct competition to Biosuccess, each of the defendants has converted for their own use, Biosuccess's trade secrets and confidential information.

121. Biosuccess is entitled to an order that the defendants cease and desist all use and disposition of its trade secrets and confidential information in connection with PD-616.

122. As a direct and proximate result of the Defendants' acts of conversion, Biosuccess has suffered damages due to, among other things, the lost value of its trade secrets and confidential information.

123. The Defendants' conversion of Biosuccess's property is oppressive and

malicious. As a result of such conduct, Biosuccess is entitled to punitive damages pursuant to California Civil Code § 3294 against the defendants in an amount to be proved at trial.

TWELFTH CAUSE OF ACTION

(For Conspiracy)

Against All Defendants

124. Biosuccess repeats and incorporates by reference the allegations in the paragraphs above, as if fully set forth herein.

125. Biosuccess is informed and believes, and on that basis alleges, that, in connection with the Defendants' research and development of PD-616, all Defendants agreed to a common plan to, among other things, infringe Biosuccess's patent and copyright interests, misappropriate Biosuccess's trade secrets, convert Biosuccess's confidential and proprietary information for their own use, and commit the other tortious conduct described in this Complaint.

126. Biosuccess is informed and believes, and on that basis alleges, that Defendants had actual knowledge that such tortious conduct would occur and concurred in the scheme with knowledge of its unlawful purpose.

127. Biosuccess is informed and believes, and on that basis alleges, that in agreeing to commit such tortious conduct against Biosuccess, Defendants acted for their own individual advantage by disclosing and exploiting Biosuccess's trade secrets and other confidential and proprietary information for their own personal gain.

128. As a direct and proximate result of Defendants' conspiracy to commit such tortious conduct, Biosuccess has suffered damages in an amount to be proved at trial.

129. Defendants' conspiracy to commit tortious conduct against Biosuccess renders each of them liable for all acts taken by their co-conspirators before and after each defendant joined the conspiracy.

THIRTEENTH CAUSE OF ACTION

(For Aiding and Abetting)

Against All Defendants

130. Biosuccess repeats and incorporates by reference the allegations in the paragraphs above, as if fully set forth herein.

131. Biosuccess is informed and believes, and on that basis alleges, that defendants knew disclosure of Biosuccess's trade secrets and other confidential and proprietary information would violate non-disclosure agreements and would constitute a breach of fiduciary duties, conversion, misappropriation, and the other wrongs described herein.

132. Biosuccess is informed and believes, and on that basis alleges, that in connection with setting up the new companies to research and develop PD-616, defendants gave substantial assistance and encouragement to the other defendants to unlawfully disclose Biosuccess's trade secrets and other confidential and proprietary information.

133. Biosuccess is informed and believes, and on that basis alleges, that the defendants' mutual assistance and encouragement was a substantial factor causing the disclosure of Biosuccess's trade secrets and other proprietary and confidential information and, therefore, was a substantial factor in causing harm to Biosuccess.

134. By such conduct, each Defendant aided and abetted the other Defendants in breaching their fiduciary duties to Biosuccess, converting Biosuccess's property for their own use, and committing the other wrongs described herein. All Defendants are therefore jointly responsible for the wrongful conduct of any of the other defendants in this Complaint.

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PRAYER FOR RELIEF

WHEREFORE, BIOSUCCESS prays for the following relief:

A. That the Court enters judgment in favor of Biosuccess and against Defendants;

B. That the Court determine that Defendants have committed patent and copyright infringement;

C. That Defendants, their officers, agents, servants, employees, and all persons in active concert or participation with them, be preliminarily and permanently restrained and enjoined from misappropriating, disclosing, or using Biosuccess's confidential information and trade secrets, and from infringing Biosuccess's patent and copyright interests;

E. That Biosuccess recover compensatory damages for Defendants' wrongdoing in an amount to be established at trial, together with pre-judgment and post-judgment interest thereon at the maximum legal rate;

G. That Biosuccess recover its proven damages or statutory damages elected in accordance with the Patent Act, 35 U.S.C. §§284 and 285 and the Copyright Act, 17 U.S.C. §§ 504 and 505 and other applicable law.

H. That Biosuccess recover an award of punitive and other appropriate exemplary damages, disgorgement, restitution, pre-judgment and post-judgment interest as permitted by statute and/or contract;

I. That Biosuccess recover attorneys' fees and the costs of suit herein;

J. An award of treble damages under 35 U.S.C. § 284; and

K. Such other and further relief as this Court may deem just and proper.

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DEMAND FOR A JURY TRIAL

Plaintiff Biosuccess hereby demands a jury trial on all issues so triable.

Dated: January 14, 2014

LEE TRAN LIANG & WANG LLP

By: _____
Enoch H. Liang
Attorneys for Plaintiff
BIOSUCCESS BIOTECH, CO., LTD.

EXHIBIT A

About Us

Founded in 2005, Biosuccess Biotech Co. Ltd. is a privately held company. It focuses on the development of PD-616 (12-O-tetradecanoylphorbol-13-acetate, also known as TPA) for the treatment of AML and AIDS/HIV. The work of two scientists, Prof. Richard Chang & Prof. Zhang Tao Han sustained by their knowledge of this agent's characteristics and their wide experience of years is the basis for the company's interest in using PD-616 in treatment.

AML Studies with TPA (PD-616)

Clinical studies were conducted in China in patients who had few (sometimes none) remaining options for therapy in acute myelogenous leukemia (AML). These patients were refractory to standard therapy and had debilitating symptoms. **Findings showed that some patients were put into partial remission and established the short term safety for the intravenous administration of PD-616.**

Encouraged by the clinical results from China, Roger Strair MD, PhD, a leading oncologist at The Cancer Institute of New Jersey (CINJ), at the University of Medicine and Dentistry of N.J. (UMDNJ), obtained an investigator IND, and conducted a Phase 1 study in patients the majority of whom also had relapsed/refractory AML. Based on Phase 1 findings, Biosuccess Biotech was encouraged by Dr. Strair to conduct a Phase 2 study in relapsed/refractory AML. Currently, a Phase 2 study is underway and the recruitment of refractory AML patients is actively done by Dr. Strair.

AIDS/HIV Studies with TPA (PD-616)

Three preliminary experiments, part of the clinical research process, were conducted in China on AIDS/HIV. These patients had few treatment options, as they presented many of the injurious effects of this disease and were refractory to standard anti-AIDS drugs. **Following treatment with PD-616, there was a disappearance of symptoms and a return to normal in almost all patients. In the third clinical study, the number of CD4 T-cells was somewhat reduced while the concentration of the virus in blood increased in all patients in 30 days after starting PD-616 treatment, but was almost undetectable at 60 days.** These results are clinical evidence that support the unique mechanism of action proposed for PD-616 in AIDS/HIV. Future clinical studies are needed, but it appears that PD-616 can be a totally new and highly effective drug for the treatment of AIDS. In order to confirm these clinical findings, Biosuccess Biotech Co. Ltd. has plans to conduct rigorously controlled clinical trials in the U.S. during a large Phase 2 study.

Legal Grounds

Biosuccess Biotech is protected by an issued "use patent" that provides sole rights to use the intravenous administration of PD-616 for therapeutic purposes (2001).

A patent application was filed on the use of PD-616 to treat AML in January, 2007. In January, 2008, a patent application was filed for the use of PD-616 in HIV/AIDS and includes coverage of many other phorbol ester structures in the PD-616 chemical class.

Biosuccess Biotech Co. Ltd. has 20 years exclusive rights to the use of PD-616 in AML and HIV/AIDS, beginning with January 30th, 2008.

In June 2011, AML Phase 2 protocol was approved by FDA.

Company History
Leadership Team

Latest News

April 27th, 2012
Biosuccess has received an IND approval from the FDA. An Acute Myelocytic Leukemia (AML) study under this IND will be underway shortly.

March 23rd, 2012
A corporate IND has been submitted to the FDA for use of TPA in Acute Myelocytic Leukemia (AML).

June 16th, 2011
Jace Chew joins our team as President of ASEAN, India sub-continent and Australia operations.

June 16th, 2011
AML Phase 2 trial begins recruiting patients.

Read More News

RICH PHARMACEUTICALS

About Us

Rich Pharmaceuticals is a biopharmaceutical company that became a public entity August 26, 2012 as a result of a reverse merger with Nepia Inc. The Company is focused on the development of its lead product, TPA (12-O-tetradecanoylphorbol-13-acetate), for the treatment of acute myelogenous leukemia (AML) in refractory patients, and the reversal of physical disabilities resulting from stroke. The basis for the interest of the Company to pursue clinical development of TPA in these and possibly other indications is the result of the work of two scientists, Prof. Richard Chang and Prof. Zhang Tao Han. Both have conducted research on TPA for many years and have become experts in the characteristics of this molecule. Their findings form the scientific basis for the clinical use of TPA.

AML Studies with TPA

Initially, clinical studies were conducted in leading hospitals in China in patients who had few, if any, options remaining for the treatment of AML. These patients were refractory to standard therapy and had debilitating symptoms that were life threatening. The clinical status of some of the patients treated with TPA changed favorably to partial remission. In addition, the short term safety of TPA was established in these individuals using an intravenous formulation of TPA.

Encouraged by the clinical results with TPA in China, Roger Strair MD, PhD, a leading oncologist at the University of Medicine and Dentistry at Rutgers University, obtained an investigator IND and successfully completed a Phase 1 study in patients, the majority of whom had relapsed/refractory AML. Rich Pharmaceuticals was encouraged by Dr. Strair to conduct a Phase 2 study in relapsed/refractory AML. A Phase 2 study is currently underway under the direction of Dr. Strair who is actively enrolling appropriate patients in this study.

Legal Grounds

Rich Pharmaceuticals is protected by an issued “use patent” that gives sole rights to the Company to use the intravenous administration of TPA for therapeutic purposes. Since TPA can only be administered for therapeutic purposes by this route, this patent provides complete protection for the use of TPA for any other use.

About Us

Company History
Leadership Team

News

October 2nd, 2013
Rich Pharmaceuticals Inc. has been licensed to pursue the clinical development of their lead drug, TPA, in acute myelogenous leukemia (AML) and stroke.

October 1st, 2013
Rich Pharmaceuticals appoints Robert Thomas as COO

September 6th, 2013
Rich Pharmaceuticals appoints David Chou, Phd. to the Board of Director

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Morbi accumsan convallis est, sit amet varius sapien commodo.

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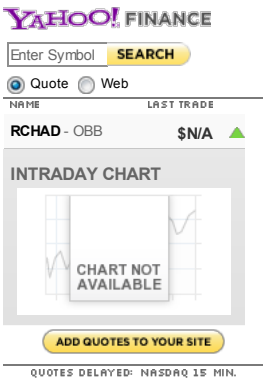
Stock Ticker



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Contact Rich Pharmaceuticals by going to our contact us page.

Sitemap

About Us
Technology
Studies
Patients
Medical Professionals
News
Investor Information
Contact Us

Resources

Leadership Team
Frequently Asked Questions

EXHIBIT B

Rich Pharmaceuticals

About Us

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In June 2011, AML Phase 2 protocol was approved by FDA.

Company History
Leadership Team

Latest News

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EXHIBIT C

US006063814A

United States Patent [19]

Chang et al.

[11] Patent Number: 6,063,814

[45] Date of Patent: May 16, 2000

[54] **PHORBOL ESTERS AS ANTI-NEOPLASTIC AND WHITE BLOOD CELL ELEVATING AGENTS**

[76] Inventors: **Richard L. Chang**, 107 Konner Ave., Pine Brook, N.J. 07058; **Zheng Tao Han**, 4 Dongming Road, Zheng Zhou, Henan, China

[21] Appl. No.: **08/837,085**

[22] Filed: **Apr. 14, 1997**

[51] **Int. Cl.**[7] **A61K 31/21**

[52] **U.S. Cl.** **514/510**

[58] **Field of Search** 514/510

[56] **References Cited**

PUBLICATIONS

Shih et al., Carcinogenesis (1993), 14(4), 709–12, 1993.

Primary Examiner—Jerome D. Goldberg
Attorney, Agent, or Firm—Bernard S. Leon

[57] **ABSTRACT**

Phorbol esters and particularly phorbol-12-myristate-13-acetate (TPA) are described as effective in treating patients with neoplastic diseases such as leukemia as well as in increasing the white blood cell count.

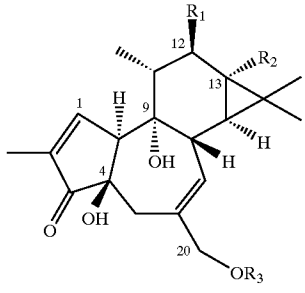
20 Claims, No Drawings

PHORBOL ESTERS AS ANTI-NEOPLASTIC AND WHITE BLOOD CELL ELEVATING AGENTS

BRIEF DESCRIPTION OF THE INVENTION

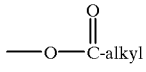
The invention relates to treating neoplastic disease such as leukemia and increasing the white blood cell counts in patients suffering from neoplastic diseases or undergoing chemotherapy by a method which comprises administering parenterally to patients an effective amount of a phorbol ester of the Formula:

I

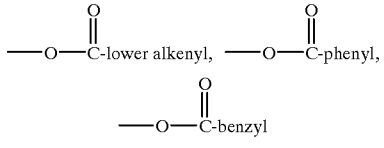


or isomers thereof

wherein R_1 and R_2 are selected from the group consisting of hydrogen,

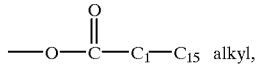


wherein the alkyl group contains 1 to 15 carbon atoms,

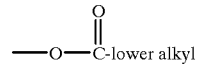


and substituted derivatives thereof. At least one of R_1 and R_2 is other than hydrogen and R_3 is selected from the group consisting of hydrogen and

Preferred are Compounds of the Formula I wherein one of R_1 and R_2 is selected from the group consisting of

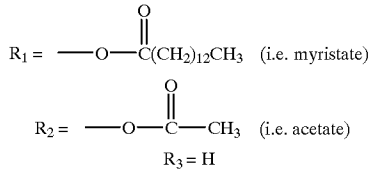


more preferably higher chain alkyl groups, especially decanoate or myristate and the other is



and R_3 is hydrogen.

Especially preferred is a compound of the formula I where



i.e. phorbol-12-myristate-13-acetate or as it is also known 12-O-tetradecanoylphorbol-13-acetate (herein TPA)

The term "lower alkyl" or "lower alkenyl" as used herein shall mean moieties containing 1–7 carbon atoms. In the Compounds of the Formula I, the alkyl or alkenyl groups may be straight or branched chain and preferably contain at least one of R_1 or R_2, a long chain carbon moiety (decanoate or myristate).

The alkyl, alkenyl, phenyl and benzyl groups may be unsubstituted or substituted with halogen, preferably, chlorine, fluorine or bromine, nitro, amino and similar type radicals.

BACKGROUND OF THE INVENTION

The compounds of the Formula I are generally known to be tumor promoters and as being highly irritant to skin and the mucous membrane.

The preferred exemplar TPA is a biologically active natural compound which can be extracted from croton oil. TPA has been known for many years to be a co-carcinogen or tumor promoter. See Merck Index, 11th Edition, Page 1164 No. 7306. It is also known to be a highly potent irritant to skin and to be harmful if ingested orally. In a product brochure distributed by Chemsyn Science Laboratories of Lenexa, Kansas, TPA is described as an extremely potent mouse skin cancer promoter and as a powerful mitogen in cell cultures. The product brochure warns the user to treat TPA with extreme care. The literature discloses that TPA induces differentiation in the stable human promyelocytic leukemic cell line HL-60. Weinberg, JP (Science 213:655–657, 1981) further discloses that TPA causes differentiation of cells of the human leukemia cell line HL-60 to nondividing macrophage-like cells. These differentiated cells are cytotoxic for tumor cells including current, untreated HL-60 cells in vitro. However, nowhere in the prior art has it been suggested that compounds of the Formula I when delivered parenterally to humans would be effective in treating neoplastic diseases or in raising the white blood cell count, much less without significant unwanted side effects.

Leukemia is a neoplastic disease in which white corpuscle maturation is arrested at a primitive stage of cell development. The disease is characterized by an increased number of leukemic blast cells in the bone marrow and by varying degrees of failure to produce normal hematopoietic cells. The condition may be either acute or chronic. Leukemias are further typically characterized as being lymphocytic or myelocytic. Acute lymphocytic leukemia (ALL) arises in lymphoid tissues and ordinarily first manifests its presence in bone marrow. Acute myelocytic leukemia (AML) arises

from bone marrow hematopoietic stem cells or their progeny. The term "acute myelocytic leukemia" subsumes several subtypes of leukemia e.g. myeloblastic leukemia, promyelocytic leukemia and myelomonocytic leukemia.

Chronic myelogenous leukemia is characterized by abnormal proliferation of immature granulocytes, for example, neutrophils, eosinophils and basophils, in the blood, bone marrow, the spleen, liver and sometimes in other tissues. A large portion of chronic myelogenous leukemia patients develop a transformation into a pattern indistinguishable from the acute form of the disease. This change is known as the "blast crises": The present invention is generally suitable for treating leukemias, as well as other neoplastic diseases.

DETAILED DESCRIPTION OF THE INVENTION

Compounds of the Formula I are useful as anti-tumor agents in patients suffering from neoplastic diseases and for raising the white blood cell count in patients suffering from neoplastic diseases such as leukemia and other forms of tumors such as solid tumors and undergoing chemotherapy.

The preferred compound TPA has demonstrated in humans the ability to reduce the abnormal bone marrow profile in patients with AML and other types of leukemia to the point where the patient can be considered to be in remission. Of the patients treated with TPA, all had been diagnosed as having progressed to an acute form of leukemia and the prognosis for a favorable outcome was not very bright. Prior to the administration of TPA, all of the patients had received various forms of conventional chemotherapy including hydroxyurea, busulfan and Ara-C etc without success originally or because of the development of resistance to these drugs. Upon administration of TPA to these refractory patients, clinical remission was achieved in a relatively short time. In addition, during and after the treatment with TPA, there was no bone marrow suppression, infection or bleeding. Many of the patients have been in clinical remission for over six months from the time the treatment with TPA first started.

Additionally, the Compounds of the Formula I can be used to treat patients who are undergoing chemotherapy for the treatment of solid tumors as a method of elevating their white blood cell counts (leukocytes). Chemotherapeutic agents are known to exert toxic effects on certain normal cells in the body. The white blood cells in the body that are responsible for helping the body fight off infections are especially sensitive to chemotherapeutic agents. If these infection fighting cells, (the white blood cells) fall to very low levels in the patient receiving chemotherapy, the patient will become more susceptible to serious infection. TPA has shown the propensity to help speed the rapid recovery of the infection fighting cells, both after and during chemotherapy treatment and therefore TPA is especially useful in reducing the chances of a patient developing serious infections. Often the elevation of the white blood cell count occurs within one day of treatment. The present invention is useful in raising the white blood cell count in patients undergoing chemotherapy for all types of solid tumors such as breast, lung, prostate and colon cancers. TPA helps to maintain adequate levels of white blood cells or infection fighting cells. These cells work by surrounding and destroying bacteria that may have entered the body. TPA, by preventing the number of white blood cells from falling to low levels for long periods of time, lessens the potential for infection, the use of antibiotics and longer hospital stays. Generally by increasing the white blood cell count, the body is reprovided with an important component of its immune system.

Because of the ability to elevate the white blood cell count, the present invention may also be useful in any patient with compromised white blood counts including patients suffering from AIDS.

Also, compounds of the Formulatabove in animal studies have evidenced the ability to inhibit solid tumor growth in laboratory animals.

Dosage delivery systems, preferably aqueous dosage delivery systems, suitable for parenteral administration of compounds of the Formula I in a pharmaceutical acceptable carrier, can be prepared by dissolving a Compound of the Formula I in an appropriate solvent which is miscible, dispersable or soluble with water, such as an alcohol eg. ethanol, propanol, isopropanol and the like. Other water soluble solvents suitable for the purpose of the present invention include glycols such as propylene glycol or polyethylene glycol, glycerine (glycerol), glycerolformal and the like. There can be added to the dosage forms antimicrobial preservatives such as benzyl alcohol, phenol, cresol (ortho, meta or para or mixtures of the foregoing) and phenylethylalcohol. There can also be added low concentrations of surfactants known to be suitable for intravenous use at low concentrations including Emulphor EL-620, Cremophor EL, Polysorbate 80 (Tween 80) or Polysorbate 20 (Tween 20).

Any solvent or mixtures of solvents and/or preservative and/or surfactant can be selected by the person skilled in the art as the pharmaceutically acceptable carrier in accordance with conventional practices for preparing parenteral dosage formulations. All that is required of a component of the pharmaceutically acceptable carrier to be suitable for the purposes of the present invention is that it be safe when injected into a human; is miscible, dispersible or soluble in water; has no cytotoxicity; and does not diminish the shelf life of the pharmaceutical formulation so that it may be stored.

The compounds of the Formula I in the treatment of neoplastic diseases such as leukemia or for raising white blood cell counts can be administered parenterally (I.V.) in dosage amounts from about 0.001 mg per dose to about 1.5 mg per dose, for about 1–7 times per week for about 1–10 weeks; more preferable from about 0.05 to about 1 mg, 1–7 times per week, for 1–7 weeks; and still more preferably from about 0.1 mg to about 0.6 mg, 1–7 times per week for about 1–7 weeks. The most preferred dosage form is delivered through I.V. infusion and contains 0.1 mg, 0.25 mg or 0.5 mg per dose. The course of therapy preferred is 1–7 weeks with 1 mg being administered over a week in divided doses.

In patients receiving chemotherapy for solid tumors, the most preferred time for administrating a single dose of a compound of the Formula I is about the time the patient is to receive or has just undergone a course of chemotherapy designed to combat the solid tumors.

The precise dosage amount and the duration of administration of a compound of the Formula I will depend on the exigencies of the medical situation and the judgement of the physician treating the patient in accordance with conventional practice among medical professionals. The exact dose will depend upon such factors as the age, weight and condition of the patient, the frequency of administration and the manner in which the patient responds to the treatment.

EXAMPLE I

The following compounds are illustrative of the compounds encompassed by Formula I which are suitable for the purposes of the present invention. These compounds are commercially available.

1) Phorbol 13-Butyrate
2) Phorbol 12-Decanoate
3) Phorbol 13-Decanoate
4) Phorbol 12,13-Diacetate
5) Phorbol 13,20-Diacetate
6) Phorbol 12,13-Dibenzoate
7) Phorbol 12,13-Dibutyrate
8) Phorbol 12,13-Didecanoate
9) Phorbol 12,13-Dihexanoate
10) Phorbol 12,13-Dipropionate
11) Phorbol 12-Myristate
12) Phorbol 13-Myristate
13) Phorbol 12-Myristate-13-Acetate (also known as TPA or PMA)
14) Phorbol 12,13,20-Triacetate
15) 12-Deoxyphorbol 13-Angelate
16) 12-Deoxyphorbol 13-Angelate 20-Acetate
17) 12-Deoxyphorbol 13-Isobutyrate
18) 12-Deoxyphorbol 13-Isobutyrate-20-Acetate
19) 12-Deoxyphorbol 13-Phenylacetate
20) 12-Deoxyphorbol 13-Phenylacetate 20-Acetate
21)12-Deoxyphorbol 13-Tetradecanoate
22) Phorbol 12-Tigliate 13-Decanoate
23) 12-Deoxyphorbol 13-Acetate
24) Phorbol 12-Acetate
25) Phorbol 13-Acetate

EXAMPLE 2

Formulation Type A

0.10, 0.125, 0.25 or 0.5 mg of TPA was dissolved in 1.3 ml 95–100% U.S.P. ethanol and 0.7 ml saline. Under sterile conditions, TPA was first dissolved in ethanol, then saline was added, mixed vigorously, bacteriologically filtered, and stored in sealed sterile amber vials containing either 0.10 mg/2 ml, 0.125 ml/2 ml or 0.25 mg/2 ml, 0.5 mg/2 ml.

Formulation Type B

0.10, 0.125, 0.25 or 0.5 mg of TPA was dissolved in 0.2 ml of ethanol, 1.2 ml of isopropanol and 0.6 ml saline. Under sterile conditions, TPA was first dissolved in the ethanol and isopropanol, then saline was added, and the mixture was vigorously mixed, bacteriologically filtered and stored in sealed sterile amber vials containing either 0.10 mg/2 ml, 0.125 ml/2 ml or 0.25 mg/2 ml or 0.5 mg/2 ml.

Analytical results showed that there is no chemical change in the TPA solutions stored in the dark at cold temperature for up to one year; also, there is no chemical change in the TPA solutions stored in the dark at room temperature up to two months.

EXAMPLE 3

1. Effect of TPA in a Human Promyelocytic Leukemia Cell Line (HL-60):

HL-60 cells at 2×10^6 cells/ml were treated with TPA. The final concentrations of TPA were 10, 20, or 100 ng/ml. The ethanol content was less than 0.01%. After 3 hours of TPA treatment, the cells stopped proliferating and cell aggregation and attachment to the dish were observed. After 48 h of treatment, there were morphological changes. After 4–6 days, morphological and cellular biochemical studies showed that the majority of the cells were induced to differentiate to macrophages in a dose-dependent manner.

EXAMPLE 4

(2) TPA+Low Doses of Ara-C:

The treatment of HL-60 cells with low doses of TPA (20 ng/ml) or Ara-C (100 ng/ml) demonstrated that Ara-C could induce cell differentiation, and TPA at low concentration is a weak cell differentiation-inducing agent. The combination treatment of HL-60 cells with TPA and Ara-C induced the HL-60 cells to differentiate synergistically.

EXAMPLE 5

Effect of TPA in Mice Injected With S180 (Sarcoma 180) Tumor Cells:

Eight groups of Kwen-Ming mice containing 7 mice per group were used in the following experiment. Two groups were untreated and six groups received the drug.

Each Kwen-Ming mouse was injected with 5×10^6 S180 cells at the under-arm position. After 24 or 72 h, the animals were given TPA i.p. or locally at the tumor site. The injected doses of TPA were 50, 100 and 200 μg/kg/d for 7 days. The animals were sacrificed 24 hrs after the final TPA treatment and the tumors were weighed to calculate the extent of the tumor growth inhibition. The study showed that the tumor growth was inhibited by 41.7%, 54.8% and 30.4%, respectively, in mice that were injected i.p. with 50, 100 or 200 μg/kg TPA daily for 7 days. The tumor growth was inhibited by 35.5%, 49.3% and 59.2%, respectively, in mice that were injected daily for 7 days with 50, 100 or 200 μg/kg TPA locally at the tumor site in comparison to the control mice. Pathological studies showed that the tumor cells were differentiated after the TPA treatment.

EXAMPLE 6

Effect of TPA in Mice Injected with B16 Tumor Cells:

Four groups of C57 mice were used in the experiment. Each group contained 7 mice and one group was untreated. Each C57 mouse was injected with 0.2 ml of supernatant of a 1:6 w/v homogenate of B16 cells at the under-arm position. On the third day, each treatment group was given TPA i.p. at 50, 100 or 200 μg/kg/d for 8 days. The animals were sacrificed after the treatment, the tumors were weighed, and the rates of inhibition of tumor growth were 40.0%, 59.4% and 32.1%, respectively, which were all statistically different from the control group.

EXAMPLE 7

Effect of TPA on the Peripheral White Blood Cells (WBC) and Hemoglobin (Hb) Counts in S180 Cell-Injected Mice:

S180 cells were injected into mice. On the third day, the mice were given TPA i.p. at 50, 100 or 200 μg/kg/d for 7 days. On the second day after the treatment was completed, blood samples were taken from the tails of the treated mice for WBC and Hb analyses. The WBC counts for the treated groups (50, 100, or 200 ug/kg/d for 7 d) were 16.1 ± 7.4, 18.7 ± 3.0 and $20.7\pm3.4\times10^9$/L, respectively; the WBC count for the control group was $13.6\pm1.8\times10^9$/L. The Hb of the treated groups were 136 ± 11, 149 ± 12 and 149 ± 10 g/L, and the Hb of the control group was 134 ± 15 g/L. The results indicate that i.p. injection of TPA could increase the peripheral WBC counts in mice in a dose-dependent manner, whereas the Hb levels were not greatly affected in TPA treated mice when compared to the control mice.

EXAMPLE 8

Study on the Clinical Use of TPA in Humans

1. Dose Ranging Study.

Due to the strong local irritation caused by TPA application, TPA was given to patients by i.v. infusion. TPA solution in a sterile syringe was injected into 200 ml of saline and mixed well for i.v. infusion.

2. The Toxicity and Side Effects of Different TPA Doses Administered Clinically:

(1) TPA given at 1 mg/patient/week:

One mg TPA in solution was mixed well with 200 ml of saline for i.v. infusion which was completed in 1 h at the rate of 16 μg/min. One hour after TPA administration, patients started to have chills which lasted for about 30 min, followed by fever, (the patients' temperature reached 37.5–39.5° C. which lasted for 3–5 h, then returned to normal) with light to heavy perspiration. The above symptoms could be alleviated by giving the patients glucocorticoids. TPA at this dose caused a minority of patients to bleed, several patients suffered for a short period of time difficulty in breathing, and Hb was detected in the urine. However, these side effects were short lived and reversible. The cardiac, hepatic, renal and pulmonary functions were all found to be normal.

(2) TPA given at 0.5 mg/patient×2/week: (two doses a week)

0.5 mg of TPA in solution was mixed well with 200 ml of saline for i.v. infusion which was completed in 1 h at the rate of 8 μg/min. The reactions after administration were similar to that of the 1 mg TPA dosage, but to a lesser extent than the 1 mg dose. The patients tolerated the lower dose more easily. Occasionally, Hb was detected in patients urine. Difficulty in breathing was not observed. The cardiac, hepatic, renal and pulmonary functions were all normal.

(3) TPA given at 0.25 mg/patient×4/week:

0.25 mg of TPA in solution was mixed well with 200 ml of saline for i.v. infusion which was completed in 1 h at the rate of 4 μg/min. After the administration, symptoms such as chills and fever were also observed, but to a much lesser extent than with the higher dosages. No Hb was detected in the urine, and no patient suffered difficulty in breathing. The cardiac, hepatic, renal and pulmonary functions were all normal.

After comparing the above three dosages, 0.25 mg/person×4/week and 0.5 mg/person×2/week are considered to be preferred dosages of TPA.

EXAMPLE 9

The results obtained upon treatment of patients with TPA as presented in tabular form and in subsequent examples.

TABLE 1

Clinical
Summary of Clinical Efficacy of TPA in the Five Cases Representing Chronic Myelocytic Leukemia Having Progressed to Acute Myelocytic Leukemia Before TPA Administration (Subjects 1–5) and Five Cases of Other Leukemias (Subjects 6–10)

Subject	Bone marrow Myeloblast and promyelocyte percent of total cells	
No.	Before TPA	After TPA
1	30	2.5
2	36	3.0
3	90	2.0
4	67.5	4.5
5	27.5	1.5
6	48	3
7	16	10
8	80.8	17
9	(Aplastic anemia)	(TPA terminated)
10	(9% early in TPA treatment)	0

TABLE 2

Clinical
Summary of TPA induced White Blood Cell Changes (WBC) in Patients with Solid Tumors Undergoing Chemotherapy

Subject	WBC (x 10^9/liter)	
No.	Before TPA	Peak after TPA
11	0.7	6.8
12	3.0	4.5
13	0.9	2.5
14	3.8	8.0
15	2.4	7.1
16	2.4	5.2
17	2.0	4.4
18	2.4	4.0
19	2.9	5.1
20	0.7	2.7
21	1.1	1.5
22	1.9	7.6
23	2.3	3.9
24	1.1	5.3
25	2.1	6.4
26	3.6	5.6

EXAMPLE 10

In the subjects identified as (1) through (5) below, chronic myelocytic leukemia had progressed to acute myelocytic leukemia before treatment with TPA.

Subject No. (1) T.S., male, 32, patient No. 28879. Blood profile before TPA treatment: Hb: 28 g/L; WBC: 1.0×10^9/L, platelet: 135×10^9/L. Bone marrow profile before TPA treatment: myeloblast+promyelocyte: 30%. TPA treatment: 1 mg/week (0.25 mg administered four times) for two weeks. Blood profile after treatment: Hb: 86 g/L; WBC: 2.8×10^9/L, platelet: 283×10^9/L. Bone marrow profile after TPA treatment: myeloblast+promyelocyte: 2.5%.

Subject No. (2) C.J., male, 30, patient No. 29926. Diagnosis: chronic myelocytic leukemia became acute myelocytic leukemia before treatment. Blood profile before TPA treatment: Hb: 94 g/L; WBC: 9.8×10^9/L, platelet: 63×10^9/L. Spleen: 3 cm below the rib cage. Bone marrow profile before TPA treatment: myeloblast+promyelocyte: 36%. TPA treatment: 1 mg/week for 5 weeks. Blood profile after treatment: Hb: 104 g/L; WBC: 4.9×10^9/L, platelet: 80×10^9/L. Spleen: 0.5 cm below the rib cage. Bone marrow profile after TPA treatment: myeloblast+promyelocyte: 3%.

Subject No. (3) Z.K., male, 42, patient No. 18102. Diagnosis: chronic myelocytic leukemia became acute myelocytic leukemia before treatment. Blood profile before TPA treatment: Hb: 70 g/L; WBC: 27.5×10^9/L, platelet: 21×10^9/L. Bone marrow profile before TPA treatment: myeloblast+promyelocyte: 90%. TPA treatment: 1 mg/week for 7 weeks. Blood profile after treatment: Hb: 96 g/L; WBC: 22×10^9/L, platelet: 70×10^9/L. Bone marrow profile after TPA treatment: myeloblast+promyelocyte: 2%.

Subject No. (4) W.F. male, 25, patient No. 21315. Diagnosis: chronic myelocytic leukemia became acute myelocytic leukemia before treatment. Blood profile before TPA treatment: Hb: 87 g/L; WBC: 19×10^9/L, platelet: 150×10^9/L. Bone marrow profile before TPA treatment: myeloblast+promyelocyte: 67.5%. TPA treatment: 1 mg/week for 7 weeks. Blood profile after treatment: Hb: 45 g/L; WBC: 53.5×10^9/L, platelet: 210×10^9/L. Bone marrow profile after TPA treatment: myeloblast+promyelocyte: 4.5%.

Subject No. (5) D.H., male, 38, patient No. 23965. Diagnosis: chronic myelocytic leukemia progressed to acute myelocytic leukemia. Blood profile before TPA treatment: Hb: 84 g/L; WBC: 36.6×10^9/L, platelet: 290×10^9/L. Bone marrow profile before TPA treatment: myeloblast+promyelocyte: 27.5%. TPA treatment: 1 mg/week for 2 weeks. Blood profile after treatment: Hb: 84 g/L; WBC: 27.3×10^9/L, platelet: 170×10^9/L. Bone marrow profile after TPA treatment: myeloblast+promyelocyte: 1.5%.

All the above patients had received various regimens of chemotherapy prior to the TPA treatment, including hydroxyurea, busulfan, and Ara-C, etc. but none was effective at the start of TPA treatment. Before the administration of TPA, patients received injection of 6×10^5 units of vitamin D_3 (VD_3)/person for 2 days; after the TPA administration, patients received i.v. infusion of 40 mg of Ara-C/d×3. After the treatment, the patients all achieved clinical remission in bone marrow parameters in a short time. In addition, during and after the treatment, there was no bone marrow suppression, nor infection or bleeding. These patients have been in clinical remission for over 6 months.

EXAMPLE 11

Other Types of Leukemia:

Subject No. (6) Y.P., male, 57. Diagnosed as AML-M3. Symptoms began in January, 1995. Blood profile: Hb:60 g/L, WBC: 0.4×10^9/L, platelet: 40×10^9/L. Bone marrow profile: myeloblast+promyelocyte: 48%. The TPA treatment period was 1 mg/week for three weeks, and 6×10^5 units VD_3/d×3 were injected prior to the treatment. After the first treatment period, blood profile: Hb:118 g/L, WBC: 4.1×10^9/L, platelet: 80×10^9/L. Bone marrow profile: myeloblast+promyelocyte: 3%, which met the standard for AML-M3 remission. The patient has been in remission after treatment for at least 6 months.

Subject No. (7) M.W., male, 67. Diagnosis: MDS-REAB accompanied by an increased number of monocytes. Four months of oral VP16 administration failed to produce results. The patient started to receive a combination treatment of 1,25-$(OH)_2$ VD_3 +TPA+low dose Ara-C. TPA dosage: 0.25–0.5 mg (1 mg per week) for eleven weeks. Blood profile before TPA treatment: Hb: 36 g/L; WBC: 4.0×10^9/L, platelet: 29×10^9/L. Myeloblast: 2%, Promyelocyte: 4%, Myelocyte: 3%, Neutrophil: 60%, Lymphocyte: 25%, Monocyte 6%. Bone marrow profile before treatment: active in proliferation, myeloblast: 8%, promyelocyte: 8%. Spleen: 3 cm below the rib cage. After the treatment: Spleen: 0.5 cm below the rib cage. Blood profile: Hb: 42 g/L; WBC: 10.2×10^9/L, platelet: 34×10^9/L. Neutrophil: 80%, Lymphocyte: 19%, Monocyte 1%. Promyelocytes were not detected. Bone marrow profile: active in proliferation, myeloblast: 4%, promyelocyte: 6%.

Subject No. (8) L.Q., male, 36. Diagnosis: AML-M3. Treatment with retinoic acid (RA) at 80 mg/day×50 was not successful. Blood profile before the treatment with TPA: Hb: 45 g/L, WBC: 1.0×10^9/L, platelet: 35×10^9/L. Bone marrow profile: very active in proliferation, myeloblast+promyelocyte: 80.8%. Blood profile after the TPA treatment: Hb: 66 g/L, WBC: 2.2×10^9/L, platelet: 223×10^9/L. Bone marrow profile: active in proliferation, myeloblast+promyelocyte: 17%.

Subject No. (9) Z.H., female, 21. Diagnosis: bone marrow suppression after receiving chemotherapy for chronic myelocytic leukemia, secondary aplastic anemia. The patient was treated with busulfanum (Busulfan) for 3 months. Blood profile before TPA treatment: Hb: 43 g/L, WBC: 1.6×10^9/L, platelet: 26×10^9/L. Bone marrow profile: aplastic anemia. TPA dosage: 0.25 mg×2. Blood profile after the TPA treatment: Hb: 32 g/L, WBC: 1.9×10^9/L, platelet: 57×10^9/L. Due to severe anemia, the TPA treatment was terminated.

Subject No. (10) L.N., female, 26. Diagnosis: CML. The patient had been treated with chemotherapy using the combination of homoharringtomine and Ara-C. Blood profile before TPA treatment: Hb: 98 g/L; WBC: 2.0×10^9/L, platelet: $10^2\times10^9$/L. 0.25 mg TPA administered to the patient once. Blood profile after treatment: Hb: 96 g/L; WBC: 2.0×10^9/L, platelet: 112×10^9/L. On the second day after TPA treatment: myeloblast+promyelocyte: 4%, myelocyte 5%. On the fifth day after the TPA treatment, these types of blood cells completely disappeared.

EXAMPLE 12

Patients undergoing chemotherapy for the treatment of solid tumors.

Subject No. (11) L.X., female, 50. Diagnosis: malignant lymphoma. The patient had received adramycin, vincristine, and hormonal treatment. The blood cell counts were decreased to: Hb: 78 g/L, WBC: 0.7×10^9/L, platelet: 245×10^9/L. 0.25 mg TPA was administered to the patient 4 times. The blood cell counts improved to: Hb: 76 g/L, WBC: 6.8×10^9/L, platelet: 331×10^9/L. Chemotherapy was then continued for 5 more days, and followed by one dose of 0.5 mg TPA. The WBC count was maintained at 3.0×10^9/L. The patient is still receiving treatment.

Subject No. (12) Y.G., female, 45. Diagnosis: brain tumor. Blood profile after chemotherapy was: Hb: 119 g/L, WBC: 3.0×10^9/L, platelet: 399×10^9/L. 0.25 mg TPA was given to the patient once. On the day after the TPA treatment, the blood profile was Hb: 123 g/L, WBC: 4.5×10^9/L, platelet: 436×10^9/L. The patient received further chemotherapy.

Subject No. (13) G.F., male, 60. Diagnosis: lung cancer. After chemotherapy, his blood cell counts were decreased to: Hb: 76 g/L, WBC: 0.9×10^9/L, platelet: 100×10^9/L. 0.25 mg TPA was given to the patient twice. On the day after the TPA treatment, Hb: 74 g/L, WBC: 2.5×10^9/L, platelet: 110×10^9/L. The patient is still receiving treatment.

Subject No. (14) Z.R., female, 44. Diagnosis: breast cancer. The WBC after chemotherapy was 3.8×10^9/L. 0.25 mg of TPA was given to the patient once. The WBC on the day after the TPA treatment was 8.0×10^9/L.

Subject No. (15) C.Z., female, 75. Diagnosis: Esophageal Cancer. Surgery was performed, followed by chemotherapy using cisplatin, 5-fluorouracil. Blood profile (before TPA): WBC: 2.4×10^9/L; neutrophil: 83%, lymphocyte: 17%; platelet: 150×10^9/L; RBC: 3.43×10^{12}/L; Hb: 107 g/L. TPA dosage: 0.25 mg. Blood profile (one day after TPA): WBC: 7.1×10^9/L; neutrophil: 94%; lymphocyte: 6%; platelet: 77×10^9/L; RBC: 3.33×10^{12}/L; Hb: 109 g/L. Blood profile (4 days after TPA): WBC: 4.4×10^9/L; neutrophil: 97%; lymphocyte: 3%; platelet: 105×10^9/L; RBC: 3.36×10^{12}/L, Hb: 112 g/L. Symptoms after TPA: Chill, fever, local irritation and slight headache. The cardiac, hepatic, renal and pulmonary functions were normal.

Subject No. (16) X.H., female, 60. Diagnosis: Esophageal Cancer. Surgery was performed, followed by chemotherapy using VP16, MTX, MMC and cisplatin. TPA dose: 0.25 mg. Blood profile (before TPA): WBC: 2.4×10^9/L; neutrophil: 67%; lymphocyte: 23%; platelet: 101×10^9/L; RBC: 3.45×10^{12}/L; Hb: 114 g/L. Blood profile

(one day after TPA): WBC: 5.2×10^9/L; neutrophil: 87%; lymphocyte: 13%; platelet 60×10^9/L; RBC: 3.76×10^{12}/L; Hb: 122 g/L. Blood profile (2 days after TPA administration). WBC: 4.5×10^9/L; neutrophil 80%; lymphocyte: 20%; platelet: 64×10^9/L; RBC: 2.99×10^{12}/L; Hb: 109 g/L. Symptoms after TPA: chills, fever, local irritation, cardiac, hepatic, renal and pulmonary were normal.

Subject No. (17) Y.Z., female, 37. Diagnosis: breast cancer. Surgery was performed, followed by chemotherapy using CTX, MTX, and 5-FU. TPA dose: 0.25 mg×2 (Second dose was 4 days after 1st dose). Blood profile (before TPA): WBC: 2.0×10^9/L; neutrophil: 85%; lymphocyte: 15%; platelet: 106×10^9/L; RBC: 3.24×10^{12}/L; Hb: 107 g/L. Blood profile (3 days after first TPA dose): WBC: 2.9×10^9/L; neutrophil 83%; lymphocyte: 17%; platelet: 122×10^9/L; RBC: 3.36×10^{12}/L; Hb: 107 g/L. Blood profile (2 days after second TPA dose): WBC: 3.8×10^9/L; neutrophil: 84%; lymphocyte: 16%; platelet: 84×10^9/L; RBC: 3.47×10^{12}/L. Blood profile (4 days after second TPA dose): WBC: 4.4×10^9/L; neutrophil: 86%; lymphocyte: 14%; platelet 193×10^9/L; RBC: 3.49×10^{12}/L; Hb: 112 g/L. Symptoms after TPA: patient started to have chills which lasted for 2 hrs followed by fever, temperature reached 38° C. which lasted 4 hrs and local irritation. The cardiac, hepatic, renal and pulmonary functions were normal.

Subject No. (18) H.P., male, 56. Diagnosis: Colon cancer. Surgery was performed, followed by chemotherapy using Cisplatin, VP16, and 5-FU. TPA dose: 0.25 mg×2 (2nd TPA dose was administered 24 hrs after 1st TPA dose). Blood profile (before TPA): WBC: 2.4×10^9/L; neutrophil: 63%; lymphocyte: 37%; platelet: 208×10^9/L; RBC: 4.0×10^{12}; Hb: 104 g/L. Blood profile (one day after 2nd TPA dose): WBC: 4.0×10^9/L; neutrophil: 60%; lymphocyte: 40%; platelet: 198×10^9/L; RBC: 4.1×10^{12}; Hb: 112 g/L. Symptoms after TPA: chills, fever, local irritation. Cardiac hepatic, renal and pulmonary functions were normal.

Subject No. (19) Z.T., male, 66. Diagnosis: lung cancer metastasized to adrenal gland. Surgery was performed, followed by chemotherapy using MMC, VCR, and CTX. TPA dosage: 0.25 mg×2 (2nd TPA dose was administered 24 hrs after 1st TPA dose). Blood profile (before TPA): WBC: 2.9×10^9/L; neutrophil: 76%; lymphocyte: 24%; platelet: 227×10^9/L; RBC: 3.33×10^{12}/L; Hb: 100 g/L. Blood profile (one day after second TPA dose): WBC: 5.1×10^9/L; neutrophil: 82%; lymphocyte: 18%; platelet: N/A; RBC: N/A; Hb: 93 g/L. Blood profile (2 days after 2nd TPA dose): WBC: 5.0×10^9/L; neutrophil: 80%; lymphocyte: 20%; platelet: N/A; RBC: 3.25×10^{12}; Hb: 101 g/L. Symptoms after TPA: chills, fever, local irritation. Cardiac, hepatic renal and pulmonary functions were normal.

Subject No. (20) J.Z., male, 68. Diagnosis: esophageal cancer metastasized to liver, lung and brain. The patient received chemotherapy using Taxol, cisplatin, 5-FU and Semustial. Total TPA dosage: 2mg. Blood profile (before TPA): WBC: 0.7×10^9/L; neutrophil: 29%; lymphocyte: 71%; platelet: N/A; RBC: 2.82×10^{12}/L; Hb: 87 g/L. TPA treatment schedule. On the first and third day, 0.25 mg was given and on the 5th, 7th and 9th day 0.5 mg of TPA was given. Blood profile (at day 2): WBC: 0.9×10^9/L; neutrophil: 66%; lymphocyte: 34%; platelet: 82×10^9/L; RBC: 2.17×10^{12}/L; Hb: 72 g/L. Blood profile (at day 4): WBC: 1.1×10^9/L; neutrophil: 91%; lymphocyte: 9%; platelet: 39×10^9/L; RBC: 2.09×10^{12}/L; Hb: 58 g/L. Blood profile (at day 6): WBC: 1.9×10^9/L; neutrophil: 95%; lymphocyte: 5%; platelet: 43×10^9/L; RBC: 1.9×10^{12}; Hb: 70 g/L. Blood profile (at day 8): WBC: 2.3×10^9/L; neutrophil: 91%; lymphocyte: 9%; platelet: 90×10^9/L; RBC: 1.71×10^{12}/L; Hb: 61 g/L. Blood profile (at 11th day): WBC: 2.7×10^9/L; neutrophil: 85%; lymphocyte: 15%; platelet: 37.6×10^9/L; RBC: 2.91×10^{12}/L; Hb: 61 g/L. Blood profile (at day 13): WBC: 1.9×10^9/L; neutrophil: 90%; lymphocyte: 10%; platelet: 32×10^9/L; RBC: 1.73×10^{12}/L; Hb: 57 g/L. Symptoms after TPA: Chills at 5th day which lasted about one hour. Cardiac, hepatic, renal and pulmonary functions were normal.

Subject No. (21) D.Y., female, 32. Diagnosis: lymphoma metastasized to bone marrow. The patient was treated with chemotherapy using CTX, ADM, and VCR prior to TPA treatment. TPA dosage: 0.25 mg. TPA treatment schedule: 0.25 mg of TPA was administered on days 1 and 2. 0.5 mg of TPA was administered on days 3, 5, 6 and 8. Blood profile (before TPA): WBC: 1.1×10^9/L; neutrophil: 73%; lymphocyte: 27%; platelet: 144×10^9/L; RBC: 4.15×10^{12}/L; Hb: 142 g/L. Blood profile (at day 2): WBC: 0.6×10^9/L; neutrophil: N/A; lymphocyte: N/A; platelet: 69×10^9/L; RBC: 4.15×10^{12}/L: Hb: 117 g/L. Blood profile (at day 4): WBC: 0.6×10^9/L; neutrophil: 28%; lymphocyte: 72%; platelet: 68×10^9/L; RBC: 3.95×10^{12}/L; Hb: 109 g/L. Blood profile (at day 7): WBC: 0.8×10^9/L; neutrophil: 88%; lymphocyte: 12%; platelet: 60×10^9/L; RBC: 4.22×10^{12}/L; Hb: 110 g/L. Blood profile (at day 9): WBC: 1.5×10^9/L; neutrophil: 80%; lymphocyte: 2%; platelet: 69×10^9/L; RBC: 4.02×10^{12}/L; Hb: 112 g/L. Symptoms after TPA: No chills and fever, only local irritation. Cardiac, hepatic, renal and pulmonary functions same as before TPA treatment. Since this patient's lymphoma cells had metastasized to the bone marrow, she required a high dose of TPA (2.5 mg) and a longer treatment time (9 days) in order to induce a very low level of WBC.

Subject No. (22) X.Y., female, 34. Diagnosis: Nasopharyngeal carcinoma metastasized to neck lymph node. The patient was treated with chemotherapy using 5-FU, ADM, and MMX prior to treatment with TPA. Blood profile after chemotherapy (but before TPA treatment): WBC: 1.9×10^9/L; neutrophil: 89%; lymphocyte: 11%; Hb: 118 g/L. Blood profile (one day after administration of 0.25 mg): WBC 1.8×10^9/L; neutrophil: 79%; lymphocyte: 21%; Hb: 116 g/L. Blood profile (three days after TPA administration): WBC. 2.9×10^9/L; neutrophil: 73%; lymphocyte: 27%; Hb: 123 g/L. Blood profile (7 days after TPA administration): WBC: 7.6×10^9/L; neutrophil: 82%; lymphocyte: 18%; Hb: 118 g/L. Symptoms after TPA: Chills, fever (39.2° C.) continued for 4 hrs. Liver, kidney, heart and lung were functioning normally.

Subject No. (23) J.H., male, 55. Diagnosis: stomach (cardia) cancer, reoccurred after prior surgery. The patient had received 5-FU and MMC. before treatment with TPA. Blood profile (before TPA administration): WBC: 2.3×10^9/L; neutrophil: 52%; lymphocyte: 48%; Hb: 144 g/L. Blood profile (one day after 0.25 mg TPA administration): WBC: 1.9×10^9/L; neutrophil: 53%; lymphocyte: 47%; Hb: 123 g/L. Blood profile (four days after TPA): WBC: 3.9×10^9/L; neutrophil: 44%; lymphocyte: 56%; Hb: 129 g/L. Blood profile (seven days after TPA): WBC: 3.7×10^9/L; neutrophil: 48%; lymphocyte: 52%; Hb: 138 g/L. Symptoms after TPA: No chills. Low fever (37.8° C.). Functions of liver, kidney, heart and lung were normal.

Subject No. (24) W.L., male, 62. Diagnosis: multiple myeloma. The patient had received VCR, ADM, and DXM before treatment with TPA. Blood profile (before

TPA administration): WBC: 1.1×10^9/L; neutrophil: 73%; lymphocyte: 27%; Hb: 112 g/L. Blood profile (one day after administration of 0.25 mg TPA): WBC: 5.3×10^9/L; neutrophil: 60%; lymphocyte: 40%; Hb: 139 g/L. Symptoms after TPA: No chills, no fever, no local irritation. Liver, kidney, heart and lung were functioning normally.

Subject No. (25) T.L., female, 42. Diagnosis: breast cancer. The patient received chemotherapy treatment using CTX, MMC, and 5-FU. Blood profile (before TPA): WBC: 2.1×10^9/L; neutrophil: 72%; lymphocyte: 28%; Hb: 126 g/L. Blood profile (one day after administration of 0.25 mg of TPA): WBC: 6.4×10^9/L; neutrophil: 90%; lymphocyte: 10%; Hb: 126 g/L. Symptoms after TPA administration: No chills, no fever. Injection site was red, swollen in appearance and painful probably caused by the infusion needle. The symptoms disappeared the second day after they appeared. Liver, kidney, heart and lung were functioning normally.

Subject No. (26) Q.W., male, 56. Diagnosis: esophageal cancer which had metastasized to the liver after surgery. The patient had received chemotherapy using cisplatin and taxol. TPA dosage: 0.25 mg. Blood profile (before TPA administration): WBC: 3.6×10^9/L; neutrophil: 80%; lymphocyte: 20%; Hb: 124 g/L. Blood profile (one day after TPA administration): WBC: 4.2×10^9/L; neutrophil: 83%; lymphocyte: 17%; Hb: 120 g/L. Blood profile (2 days after TPA): WBC: 5.6×10^9/L; neutrophil: 81%; lymphocyte: 19%; Hb: 116 g/L. Symptoms after TPA administration: temperature reached 39° C. which lasted 3 hr. Stomach ache and diarrhea (which disappeared soon after). The cardiac, hepatic, renal and pulmonary functions were normal.

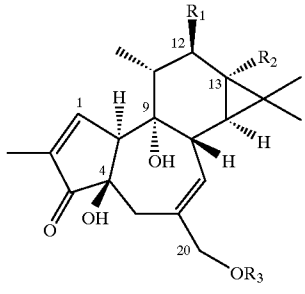
Abbreviations

VP16, Etoposide; MMC, Mitomycin C; MTX, Methotrexate; 5FU, 5-fluorouracil; CTX, Cyclophosphamide; CP, Cisplatin; VD_3, vitamin D_3; MDS-RAEB, Myelodysplastic syndrome-refractory anemia with excessor blasst; Ara-C, cytarabine; AML, Acute myelocytic leukemia; Ml, AML without differentiation; M2, AML with maturation; M3, Acute promyelocytic leukemia; M4, Acute myelomonocytic leukemia; M5, Acute monocytic leukemia; RT, Retention time; WBC, White blood cells; Hb, Hemoglobin.

What is claimed is:

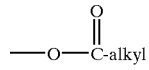
1. A method of treating leukemia which comprises administrating parenterally to patients afflicted with leukemia, an effective amount of a compound of the Formula

I

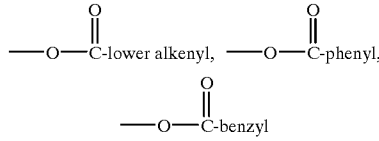


or isomers thereof

wherein R_1 and R_2 are selected from the group consisting of hydrogen,



wherein the alkyl group contains 1–15 carbon atoms,



or substituted derivatives thereof, at least one of R_1 and R_2 is other than hydrogen and R_3 as selected from the group consisting of hydrogen and

2. A method as in claim **1** wherein the effective amount is from about 0.001 mg to about 1.5 mg per single dose administered 1–7 times per week for 1–7 weeks.

3. A method as in claim **2** wherein the effective amount is from about 0.05 mg to about 1 mg. per dose delivered 1–7 times per week for 1–7 weeks.

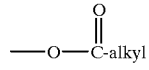
4. A method as in claim **3** wherein the effective amount is from about 0.05 mg to about 0.6 mg. per dose.

5. A method as in claim **4** wherein the effective amount is 1 mg. per week for 1–7 weeks.

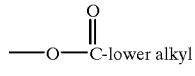
6. A method as in claim **5** wherein the leukemia is myelocytic.

7. A method as in claim **6** wherein at least one of R_1 or R_2 is decanoate or myristate.

8. A method as in claim **7** wherein one of R_1 and R_2 is



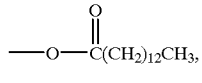
wherein the alkyl group contains 1–15 carbon atoms and the other is



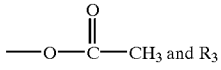
and R_3 is hydrogen.

9. A method as in claim **6** wherein the leukemia is acute myelocytic leukemia.

10. A method as in claim **9** wherein in the compound of the Formula I, R_1 is



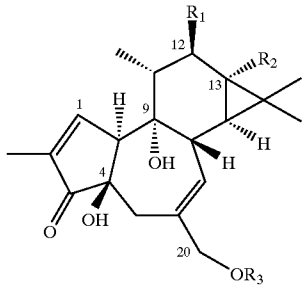
R_2 is



and R_3 is hydrogen.

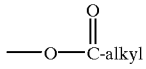
11. A pharmaceutical composition suitable for parenteral administration to humans which comprises from about 0.05 mg, to about 1.5 mg, of a Compound of the Formula

I

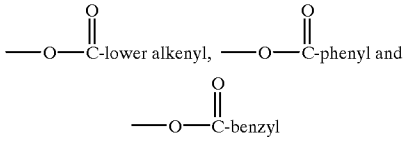


or isomers thereof

wherein R_1 and R_2 are selected from the group consisting of hydrogen



wherein the alkyl group contains 1–15 carbon atoms,



and substituted derivatives thereof, and at least one of R_1 and R_2 is other than hydrogen and R_3 is selected from the group consisting of hydrogen and

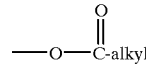
and a pharmaceutically acceptable carrier for a Compound of the Formula I.

12. A composition in claim **11** wherein the carrier is an aqueous medium.

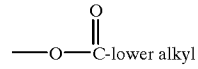
13. A composition as in claim **12** which contains from about 0.05 mg to 1.0 mg of a Compound of the Formula I.

14. A composition as in claim **12** which contains from about 0.05 mg to about 0.6 mg.

15. A composition as in claim **13** wherein one of R_1 or R_2 is

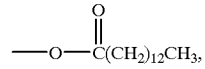


and the other is

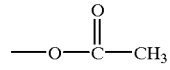


and R_3 is hydrogen.

16. A composition as in claim **14** wherein R_1 is



R_2 is



and R_3 is hydrogen.

17. A composition as in claim **11** wherein at least one of R_1 or R_2 is decanoate or myristate.

18. A composition as in claim **11** wherein the Compound of the Formula I is present in dosage amounts of 0.10 mg, 0.25 mg or 0.50 mg.

19. A composition as in claim **18** wherein the dosage form for parenteral administration is an ampoule.

20. A composition as in claim **19** wherein the Compound of the Formula I is phorbol-12-myristate-13-acetate.

* * * * *

ORIGINAL

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Central District of California

BIOSUCCESS BIOTECH, CO., LTD.,

Plaintiff(s)

v.

RICH PHARMACEUTICALS, INC., a Nevada Corporation formerly known as Nepia, Inc., IMAGIC, LLC, a California LLC, RICHARD L. CHANG HOLDINGS LLC, a New Jersey LLC, BEN CHANG, an individual, and DOES 1 through 10, inclusive,

Defendant(s)

Civil Action No. CV14-00310-PA(JCGx)

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Lee Tran Liang & Wang LLP
Enoch H. Liang / Heather F. Auyang / Lisa J. Chin
601 S. Figueroa Street, Suite 3900
Los Angeles, CA 90017
Telephone: (213) 612-8900 / Facsimile: (213) 612-3773

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

CLERK OF COURT

Date: 01/14/2014

Signature of Clerk or Deputy Clerk

1202

Civil Action No.

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☐ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

NOTICE OF ASSIGNMENT TO UNITED STATES JUDGES

This case has been assigned to District Judge Percy Anderson and the assigned Magistrate Judge is Jay C. Gandhi .

The case number on all documents filed with the Court should read as follows:

2:14-cv-00310-PA(JCGx)

Pursuant to General Order 05-07 of the United States District Court for the Central District of California, the Magistrate Judge has been designated to hear discovery related motions.

All discovery related motions should be noticed on the calendar of the Magistrate Judge.

Clerk, U. S. District Court

January 14, 2014
Date

By APEDRO
Deputy Clerk

NOTICE TO COUNSEL

A copy of this notice must be served with the summons and complaint on all defendants (if a removal action is filed, a copy of this notice must be served on all plaintiffs).

Subsequent documents must be filed at the following location:

☒ Western Division
312 N. Spring Street, G-8
Los Angeles, CA 90012

☐ Southern Division
411 West Fourth St., Ste 1053
Santa Ana, CA 92701

☐ Eastern Division
3470 Twelfth Street, Room 134
Riverside, CA 92501

Failure to file at the proper location will result in your documents being returned to you.

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

I. (a) PLAINTIFFS (Check box if you are representing yourself ☐)

BIOSUCCESS BIOTECH, CO., LTD.

DEFENDANTS (Check box if you are representing yourself ☐)

RICH PHARMACEUTICALS, INC., IMAGIC LLC, RICHARD L. CHANG HOLDINGS LLC, BEN CHANG, DOES 1 through 10

(b) County of Residence of First Listed Plaintiff Taiwan
(EXCEPT IN U.S. PLAINTIFF CASES)

County of Residence of First Listed Defendant Los Angeles, CA
(IN U.S. PLAINTIFF CASES ONLY)

(c) Attorneys (Firm Name, Address and Telephone Number) If you are representing yourself, provide the same information.

Enoch H. Liang / Heather F. Auyang / Lisa J. Chin
Lee Tran Liang & Wang LLP, 601 S. Figueroa Street, Suite 3900, Los Angeles, CA 90017, Telephone (213) 612-8900

Attorneys (Firm Name, Address and Telephone Number) If you are representing yourself, provide the same information.

II. BASIS OF JURISDICTION (Place an X in one box only.)

- ☐ 1. U.S. Government Plaintiff
- ☒ 3. Federal Question (U.S. Government Not a Party)
- ☐ 2. U.S. Government Defendant
- ☐ 4. Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only
(Place an X in one box for plaintiff and one for defendant)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business in this State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated and Principal Place of Business in Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. ORIGIN (Place an X in one box only.)

- ☒ 1. Original Proceeding
- ☐ 2. Removed from State Court
- ☐ 3. Remanded from Appellate Court
- ☐ 4. Reinstated or Reopened
- ☐ 5. Transferred from Another District (Specify)
- ☐ 6. Multi-District Litigation

V. REQUESTED IN COMPLAINT: JURY DEMAND: ☒ Yes ☐ No (Check "Yes" only if demanded in complaint.)

CLASS ACTION under F.R.Cv.P. 23: ☐ Yes ☒ No ☐ **MONEY DEMANDED IN COMPLAINT:** $

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

35 U.S.C § 1, et seq. (patent infringement); 17 U.S.C § 1, et seq. (copyright infringement); 28 U.S.C. § 1367

VII. NATURE OF SUIT (Place an X in one box only).

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce/ICC Rates/Etc.
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced & Corrupt Org.
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Info. Act
- ☐ 896 Arbitration
- ☐ 899 Admin. Procedures Act/Review of Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loan (Excl. Vet.)
- ☐ 153 Recovery of Overpayment of Vet. Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment

REAL PROPERTY CONT.
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Fed. Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury-Med Malpratice
- ☐ 365 Personal Injury-Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

TORTS PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accomodations
- ☐ 445 American with Disabilities-Employment
- ☐ 446 American with Disabilities-Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other
- ☐ 540 Mandamus/Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Mgmt. Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Ret. Inc. Security Act

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☒ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405 (g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405 (g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

FOR OFFICE USE ONLY: Case Number: CV14-00310

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

VIII. VENUE: Your answers to the questions below will determine the division of the Court to which this case will most likely be initially assigned. This initial assignment is subject to change, in accordance with the Court's General Orders, upon review by the Court of your Complaint or Notice of Removal.

Question A: Was this case removed from state court? ☐ Yes ☒ No If "no," go to Question B. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	STATE CASE WAS PENDING IN THE COUNTY OF:	INITIAL DIVISION IN CACD IS:
	☐ Los Angeles	Western
	☐ Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	Southern
	☐ Riverside or San Bernardino	Eastern

Question B: Is the United States, or one of its agencies or employees, a party to this action? ☐ Yes ☒ No If "no," go to Question C. If "yes," check the box to the right that applies, enter the corresponding division in response to Question D, below, and skip to Section IX.	If the United States, or one of its agencies or employees, is a party, is it:		INITIAL DIVISION IN CACD IS:
	A PLAINTIFF? Then check the box below for the county in which the majority of DEFENDANTS reside.	A DEFENDANT? Then check the box below for the county in which the majority of PLAINTIFFS reside.	
	☐ Los Angeles	☐ Los Angeles	Western
	☐ Ventura, Santa Barbara, or San Luis Obispo	☐ Ventura, Santa Barbara, or San Luis Obispo	Western
	☐ Orange	☐ Orange	Southern
	☐ Riverside or San Bernardino	☐ Riverside or San Bernardino	Eastern
	☐ Other	☐ Other	Western

Question C: Location of plaintiffs, defendants, and claims? (Make only one selection per row)	A. Los Angeles County	B. Ventura, Santa Barbara, or San Luis Obispo Counties	C. Orange County	D. Riverside or San Bernardino Counties	E. Outside the Central District of California	F. Other
Indicate the location in which a majority of plaintiffs reside:	☐	☐	☐	☐	☒	☐
Indicate the location in which a majority of defendants reside:	☒	☐	☐	☐	☐	☐
Indicate the location in which a majority of claims arose:	☒	☐	☐	☐	☐	☐

C.1. Is either of the following true? If so, check the one that applies:

☐ 2 or more answers in Column C

☐ only 1 answer in Column C and no answers in Column D

Your case will initially be assigned to the SOUTHERN DIVISION.
Enter "Southern" in response to Question D, below.

If none applies, answer question C2 to the right. →

C.2. Is either of the following true? If so, check the one that applies:

☐ 2 or more answers in Column D

☐ only 1 answer in Column D and no answers in Column C

Your case will initially be assigned to the EASTERN DIVISION.
Enter "Eastern" in response to Question D, below.

If none applies, go to the box below. ↓

Your case will initially be assigned to the WESTERN DIVISION.
Enter "Western" in response to Question D below.

Question D: Initial Division?	INITIAL DIVISION IN CACD
Enter the initial division determined by Question A, B, or C above: →	Western Division

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET

IX(a). IDENTICAL CASES: Has this action been previously filed **in this court** and dismissed, remanded or closed? ☒ NO ☐ YES

If yes, list case number(s): _____

IX(b). RELATED CASES: Have any cases been previously filed **in this court** that are related to the present case? ☐ NO ☒ YES

If yes, list case number(s): CV13-01340 JAK (ANx)

Civil cases are deemed related if a previously filed case and the present case:

(Check all boxes that apply)

☒ A. Arise from the same or closely related transactions, happenings, or events; or

☒ B. Call for determination of the same or substantially related or similar questions of law and fact; or

☒ C. For other reasons would entail substantial duplication of labor if heard by different judges; or

☒ D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

X. SIGNATURE OF ATTORNEY (OR SELF-REPRESENTED LITIGANT): _____ DATE: 01/14/2014

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet).

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405 (g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405 (g))